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ENGINEERING IN MEDICINE

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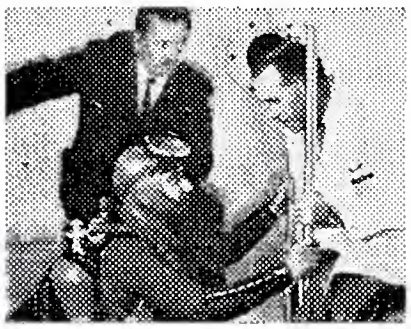

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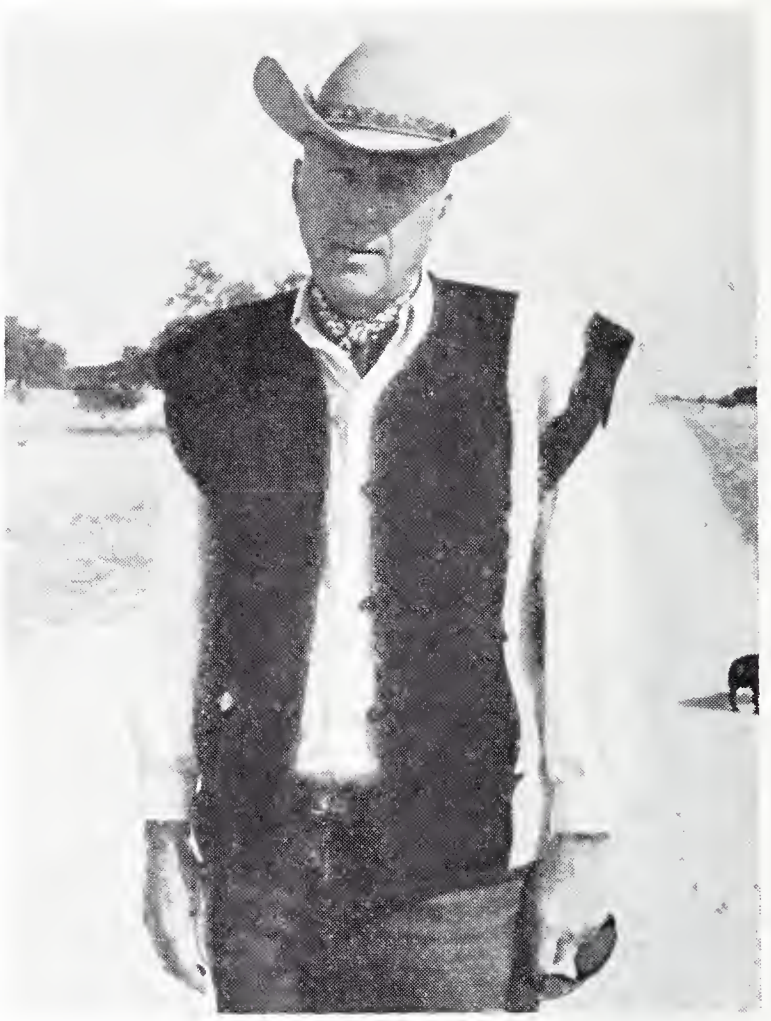
Dr. Montgomery was born on August 16, 1921, in Dallas. He graduated from Southern Methodist University in 1942 with a B.S. and received the M.D. from Columbia University in 1945. After 4 years in the U.S. Army Medical Corps he began to study Pathology. He is presently a consultant pathologist at several hospitals in and near Dallas and is a Special Assistant to the Chancellor of the University of Texas System. Dr. Montgomery has been engaged in much research which has given him insight into the role of engineering in medicine. This work includes such diverse fields as the ultraviolet properties of living tissue and the effects of weightlessness on human cells.



Guest Editorial

Engineering And Medicine

Webster's Dictionary defines Engineering as "the science by which the properties of matter and the sources of energy in nature are made useful to man in structures, machines and products". It defines Medicine as "the science and art dealing with the maintenance of health and the prevention, alleviation or cure of disease".

In recent times, more especially in the late fifties and sixties, a great deal of scientific effort and man power have been directed towards the creation of a hybrid field — Bio-engineering. This was done with the hope that the hybrid would in fact be fertile rather than sterile. This hope has not been realized, and an understanding of the failure of its realization clearly lies in an appreciation of the definition of the two fields.

Engineering is a science — Medicine is a science and an art. Engineering is concerned with putting things together in new or old ways based on well established laws — Medicine is concerned with maintaining or repairing the human organism and is based on a few laws and a great many empirical observations. The old admonition "Physician, first do no harm" finds no parallel in the thought processes of the engineer. Thus the bio-engineer has found himself to be neither engineer nor physician and as a consequence has contributed little to the science and art that is medicine.

If it be true that the marriage of Medicine and Engineering produced only the sterile hybrid — bio-engineering — then what is the proper relationship between these two vastly different activities of the human intellect and how can their interfaces — admittedly proliferating daily — be made effective?

The first point to recognize is the basic differences of the natures of the two fields as exemplified above. Having recognized these differences one should not try to meld them but rather to re-orient them towards each other. We do not need physicians who think like engineers and heaven help us if engineers ever start to think like physicians. What is required is that each appreciate the great differences in their individual approaches and then to see how progress can be made.

The second point seems to me to be that engineers only need physicians if they are sick while, physicians need engineers for a vast number of projects. From this it follows that the physician, who has engineering needs; be they in instrumentation, in artificial organ development, in systems analysis, in fabrication of new components or in materials research — must make himself knowledgeable concerning the engineer's skills and the limits of the engineer's abilities to solve his problems. To do this he must learn the rudiments of the engineer's language and translate such of his own language into these terms as is required to guide the engineer to the successful completion of the task at hand.

GUEST EDITORIAL

In the field of instrumentation the engineer has and probably will continue to make his greatest contributions to medicine. We need only site the electron microscope, the EKG machine, and the modern renal dialysis apparatus to mention a few. These accomplishments of the engineer were dictated by the need of the physician to solve a problem in "the science and art dealing with the maintenance of health".

For the efforts of the engineer to continue to be successful in the field of medicine, the engineer and the physician must work together. The physician must guide, direct, and interpret; the engineer must innovate and construct.

The successful application of these principles has enabled our laboratories to solve some very difficult technical problems. The first of these occurred in the case of the ultra-violet flying spot television microscope. The objective of this instrument is to produce and continuously record the ultra-violet absorption images of living cells without introducing sufficient ultra-violet to damage or kill the cells. At the time that we began our work, only one flying spot scanner tube was available which emitted ultra-violet light. The instrument was assembled and then it was discovered that the ultra-violet emitting scanner tube had a peak emission at 3300A°. Unfortunately, at this wave length living cells transmit virtually 100% of the light. For our work the wave length of ultra-violet needed is 2680A° because at this wave length, the nucleic acids of the cells show very strong absorption. As is frequently the case, our engineering team had perfected an instrument which did everything required from an engineering point of view, but was utterly useless from a biologic point of view. More than a year was consumed by the effort to find a phosphor with a peak emission at 2680A° so that a suitable flying spot scanner tube could be incorporated into the instrument. This having been accomplished, the apparatus now works very successfully and takes time lapse motion pictures of the ultra-violet absorption images of living cells without evidence of cellular damage.

More recently, our efforts have turned towards the space environment. Here, for the first time, we have the opportunity to study isolated human cells in a zero gravity environment. This experiment — designated S-015 by NASA — will fly on Skylab in 1973. The hardware required for its performance represents the epitome of collaboration between the physician and the engineer. The design restraints of this hardware are severe. The requirements are to design a sealed unit measuring 15x9x7 inches and weighing 24 pounds which will automatically feed and maintain at body temperature, 24 tissue cultures of living cells for 14 days and 2 tissue cultures of living cells for 30 days. The latter two tissue cultures must be automatically photographed with time lapse phase contrast microscopy every 12 hours during the 30 days. The 24 cultures must, on manual command by the astronaut, be labeled with radioactive tracers, rinsed and suitably fixed for subsequent cyto-chemistry, radio-autography and electron microscopy. To achieve this degree of sophistication in cell biology instrumentation qualified for flight required engineering solutions to many problems in microscopy, time lapse photography, micro-circuitry, and materials. One example may be given to provide some insight into these complex inter-faces. The reservoirs and the pumps to contain the media for feeding the cells must be made of a material which is unbreakable, which can be machined, can be autoclaved, and will not release substances toxic to the cells and which will not be attacked by the media. Hundreds of materials were tested for their ability to meet these criteria and the best material was found to be anodized aluminum. This is particularly remarkable because all of the reference works on tissue culture warn against the use of aluminum in any way in tissue culture.

In this brief over-view, I have tried to point out the differences between engineering and medicine and to show by example that these differences can be mutually beneficial. However, these benefits are not likely to be achieved by the hybridization of the two fields because of their basic differences. I have further emphasized that it is the physician who needs the engineer not, vice-versa. The physician of the future must learn the applicability of the tools of engineering to the field of medicine. No longer can he remain ignorant of data processing, materials research, pert charting, and systems analysis, for the efforts of others in these fields will soon leave him well behind the crest of the wave which youth must ride if the future is to yield its promise.

P. O'B. Montgomery, Jr., M.D.
Special Assistant to the Chancellor The
University of Texas System
Professor of Pathology

Editorial

Many Thanks

With this issue the U of T Medical Journal completes another academic session.

Many people have had a hand in writing, editing and handling the affairs of this present volume of The Journal, and to them I express deep gratitude.

The perennial frustrations in meeting deadlines were offset by the eventual satisfaction in putting out a quality journal which we hope has been of interest and definite value to students and graduates alike. My job would have been difficult indeed without the help of my co-editors Dave Wesson and Dave Pitel who were involved in all phases of the Journal production.

Joe Kozak did an excellent job in his first year as Advertising Manager.

Ross Gillespie (Financial Manager) and Bruno Santa-Rossa (Circulation) managed their respective duties with remarkable efficiency.

Congratulations go to the authors of the two award winning articles in this volume of the Journal.

I would like to thank all the authors of articles in the Journal and hope it has been a valuable experience for them.

I would like to thank the people at Maple Leaf Press, especially Konrad Godzinski, who looked after the production of the Journal with as much zeal as any of us Editors.

I am confident that Dave Wesson and Dave Pitel who take over as next year's Editors will produce another excellent Journal. I extend to them my best wishes and hope they receive the same assistance that they gave to me this year.

F. GENTILI

Computers In Medicine

Joel Whitton, 7T2

SECTION I

INTRODUCTION

This paper attempts to orient the student of medicine, whether possessor of an M.D. or not, towards new application areas of computers soon to be almost universally available, from private office to intensive care wards.

A Sub-Committee of the Ontario Council of Health has proposed a computerized health care delivery system[1], the report of which is soon to be integrated into a white paper for the Ontario Department of Health. Material from this report, of special interest to the young physician, is included in Section II. The report envisages a total, centrally advised, integrated, computerized health information system for the province of Ontario encompassing all areas of patient management and investigation, community health, planning, administration, research and education.

An example of a computerized acute care institution, The Hospital for Sick Children (HSC), is briefly surveyed in Section II.

COMPUTER IMPLEMENTATION PHILOSOPHY

Two points should be examined. First, the total concept: a computer system will be ineffective if developed randomly, even by priority need. The eventual operative demands and organization must be identified at the onset; implementation may be intervalled, but the conceptual system design must be known before hand. This dictum, although apparently obvious, is not always followed in applying technology to the medical sciences.

Usually in implementation, the budget is scanned first and then a solution is sought within that framework. This approach leads to a health care system which is facility-oriented and not patient-oriented; the computer becomes master and director and not a tool. The solution has been identified before a clear formulation of the problem is made.

Second, application criteria: greatest success in terms of utilization of resources, efficiency of problem solution, coherent administration, and acceptance will be achieved when computer implementation follows rational and explicit rules. For example, the problem to which the medical computer installation is to be applied must —

1) be unsolvable by the human mind (e.g. continuous acquisition and statistical analysis of cortex and brain stem evoked potentials);
2) require too much time for the physician to evaluate (e.g. multi-parameter physiological monitoring and continuous statistical patient status analysis in the intensive care unit); or at least
3) be too uneconomical or cumbersome by manual methods (e.g. patient management, medical records and history handling for a large institution, payroll, purchasing records, dietary control, etc.).

Another consideration is "power of a computer". This is not a measure of memory size or speed, but the ability to interface with many input/output devices, and the ability to perform several tasks simultaneously on a priority basis. A "mini" computer which has many "bells

and whistles" as extra features, but is only able to accept one job at a time, in serial fashion, is like a secretary, who, if typing, cannot answer the telephone until finished the entire letter; this represents a poor investment. Unfortunately, the present trend in certain institutions is for each department or research group to acquire a "maxi" problem. The pooling of resources to obtain a central, more powerful machine to be shared on an interrupt priority basis, or time-sharing basis, would ultimately be more flexible and economical.

Personnel Requirements

The application of computers in medicine is requiring more hybrid personnel, computer-oriented M.D.'s and computer analysts trained in biological and physiological sciences. Experience has been an expensive teacher that a hybrid approach is mandatory. The University of Toronto has recently responded to this requirement on both a graduate and undergraduate level. The Institute of Medical Science has a Division of Computer Science, and on an undergraduate level, the Faculty of Medicine provides electives in Computer Science.

SECTION II

Application Areas

Role of Computers in the Health Field

Report of Ontario Council of Health[1]

The report envisions Ontario segmented into health care regions each with their own computing facilities and administrative centre and each responsible for the coordination of health care within that region. It includes a master medical file on all area residents, public health data and facilities, statistics, and laboratory control. All hospitals, clinics, private practice suites, labs and public health centres within that region would input data to the computer system which would then be available to authorized personnel for analysis, control, research, recall and update for continuing patient management. Several districts will form a region with common administrative control and data banks. Medical records on an individual would be transferred to another district or region should the person move. Summarized statistics on records, care and management would be located in a provincial centre.

Thus, with regard to health care, an individual's summarized medical history would be available on entering a person's identifying information to authorized personnel anywhere in Ontario. The locations of details within the record are also referenced. Within the report, provisions are made to determine authority of data recall, and the ability of a person to inspect his record and correct, update or delete, through a physician, entries if desired. All modifications would be flagged. Community health care would be improved and accurate, central statistics for teaching, research, and government planning would be available.

Region Toronto

One regional centre in Toronto utilizes computing facilities within The Hospital for Sick Children (Figure 1). Although, still experimental and in its infancy, Region Toronto is serving the majority of the U. of T. Teaching Hospitals in their computer requirements. Region Toronto has its own administrative centre and rents time from the HSC computers for its inter-and-intra hospital requirements.

As new applications arise within a region hospital, that hospital programming team develops the solution and turns it over to region for eventual execution. A more efficient approach will eventually occur with the acquisition by region of a team of hybrid programmers and consultants which will allow a more productive and active interchange of ideas, methods and solutions between hospitals. Through Region Toronto all health care centres will thus have access to personnel familiar with medical-computer applications in the data processing and scientific areas. In the interim, that need, for those centres who recognize the problem, is being serviced to a certain extent by external agencies. Facets, an interdisciplinary biomedical engineering consulting company, is such an agency.

Figure 1

SECTION III

Computer Department HSC

Organization

The Computer Department has two major groups, General Computer Services, which handles patient data and business applications; and Scientific Computer Services responsible for real-time, on-line patient monitoring and physiological data analysis. Four computers are currently available: Nova, PDP-8, an IBM/360-40, and an IBM/1800, a process controller. Both IBM computers have keyboard data entry and television monitor displays, and the display system for the 1800 has graphic display capabilities as well as alphanumeric.

Following is a description of planned or present applications.

General Computer Services has developed the Patient Oriented Information System and Environment (POISE) system for the assemblage and utilization of a patient medical record. Data with respect to admission, history, examination, investigation and lab data, dietary control,

pharmacy — all areas of care and management — is centralized and soon to be made available to all wards and care areas by television display (See Figure 1), and, as is now, printed reports. POISE, in its design, expedites patient data cross-reference for accurate and efficient care and management. In business applications, almost all departments are aided in administrative function by computer data processing facilities.

Scientific Computer Services has spent the last two years developing a computer software system to control what will ultimately be one of the most complex and sophisticated on-line patient data monitoring systems on this continent. Areas of application include Cardiology, Pulmonary Function, and Neurology.

Cardiology. A system for assessing cardiac output using a dye-dilution technique has been developed for the PDP-8. In this technique a densitometer is used for assessing the concentration of dye within the blood following an intravenous injection. By constructing and examining the area under the time-density curve cardiac output during dye injection is assessed. An extension to this which is currently under development, will be the simultaneous acquisition of aortic and central venous pressure and cardiac rate. This will allow assessment of cardiac work, vascular resistance, and cardiac index.

Another project involves the diagnosis of anatomical heart defects. By examining serial matricies from a scintillation camera following the injection of xenon X133 gas, heart chambers are outlined. In the normal situation only the right side of the heart is outlined and if shadows from the left side are seen a shunt must exist. This application is important, for example, in assessing whether a Tetralogy of Fallot is correctable or non-correctable.

A third project, under active development, is a non-invasive technique for determining cardiac output. In the cardiovascular operating room three electrical signals, the electrocardiogram, phonocardiagram, and carotid ballistogram will simultaneously be acquired on-line by the IBM 1800. The isometric ventricular contraction time plus the volumetric ventricular contraction time is the time interval between the Q wave of the ECG and the onset of the second heart sound. From this time is subtracted the ejection period as calculated from the ballistogram. The resulting time is called the Pre-Ejection Period. The cardiac contractility or Isometric-Time-Tension Index is proportional to $1/PEP^2$. This index is important in assessing when a patient may be removed from the heart by-pass in the operating room.

Pulmonary Physiology. On-line inspiratory and expiratory lung resistance is currently being evaluated routinely. The technique used requires modulation of the air-way with a 5Hz pump; this cancels the reactive component of the air-way as 5Hz is the resonant frequency. Then by sampling at appropriate time points the resistive component can be extracted from the data. All this can be accomplished within one respiratory cycle. Although an older technique previously unusable on uncooperative paediatric subjects, the application with the computer now allows rapid and accurate analysis.

Within the Intensive Care Unit, dynamic lung compliance will be assessed by analysing the differential flow from the respirator over the differential esophageal pressure.

Programs for calculating pulmonary shunts have recently been developed. The input to this program is Hgb, PCO_2, A-V, PO_2, pH, base excess, atmospheric pressure and the desired arterial PO_2. The output is the FIO_2 required from the ventilator, and an index of interpulmonary shunts.

Biochemistry. A Stat Reporting System for biochemistry data obtained in the ICU or for the neo-natal ward has been developed and uses television monitors and keyboards for data entry. Retrieval of stored data is available at any care area with a television monitor. (Figure 2)

Acid-base balance and classification of electrolyte disturbances is determined via the terminals. A program for testing the probability of survival is also used on our neo-natal ward. Input for this last program includes gestation time, birth weight, respiratory rate, pH, temperature, PO_2, and PCO_2. Stat analysis of blood gas results is also available.

The Department of Otolaryngology. Dr. David Mitchell, Otolaryngologist-in-Chief, has supported one of the most sophisticated computer applications within the hospital. All patient history data, laboratory results, examination, audiologic assessment, operative procedures, and follow-through are gathered via a monitor and keyboard for summarization by the computer. A report is sent to ENT wards and is stored on magnetic tape. This stored data will be available for long term research studies and teaching. The Department of Cardiology has a similar system but data is entered by computer cards.

The acquisition and analysis of average evoked potentials is performed by the IBM 1800. These tests are completely under control of the computer with input being the only initial parameter setting. Stimuli include auditory, visual and tactile sensations. Facilities are available for assessing end organ and cortex responses (Figure 3). The various statistical work performed on the input electrical data is summarized in Figure 4. This extensive evaluation is required for the assessment of the paediatric subject, for unlike the cooperative adult with a mature central nervous system, the paediatric patient presents a special problem to the neurophysiologist.

Although the above descriptions are necessarily brief, the applications are not simple nor uncomplicated. Each require close cooperation between hybrid personnel and clinicians to achieve confidence and accuracy in the system.

PLEASE ENTER TEST VALUES

(N.S.Q. - 999999, Pending - 888888, Remove - 777777)

Sugar or Glucose, never both

SPECIMEN NO.	(6 Digits)	123456
SPECIMEN TYPE	(1 Letter E G A V C F O)	A
HISTORY NO.	(6 Digits)	777777
PATIENT NAME	(First 4 Letters Stored)	BILL
TIME	(00 01-24 00)	
PH	(6 90-8 20)	7.4
PCO_2	(10 - 150)	40
PO_2	(10 - 500)	90
$F10_2$	(0 10-1 00)	
NA	(110 - 185)	140
K	(1.9 - 8.9)	
CA	(4.5 - 15.5)	
B. SUGAR	(5 - 1500)	130
GLUCOSE	(5 - 1500)	
BILIRUBIN	(0.3 - 50.0)	5
TEMPERATURE	(32 0-42 0)	36.8

FOR STORAGE TYPE Y ELSE N.

(Flags E - Wrong Entry, ** - Value Outside Limits)

Figure 2

AUDIOLOGY

I *Patient History Programme*

II *Evoked Response Programmes*

Possible Stimuli	*Possible Responses*
AUDITORY	cochlear microphonic action potential brain stem response cortex response
VISUAL	electroretinogram cortex response
VIBROTACTILE	cortex response

Figure 3A

AUDIOLOGY

Possible Analyses

— Average Response with S.D., S.E., Max. & Min. points
— Latency with S.D., S.E. of points of Inflection
— Fournier Analysis
— Linear Discriminant Analysis between any Two Channels
— Amplitude Histograms

Figure 3B

THE HOSPITAL FOR SICK CHILDREN

HUMAN ELECTROPHYSIOLOGICAL RESPONSES OBTAINABLE WITH DIVISION OF AUDIOLOGY COMPUTER PROGRAMMES

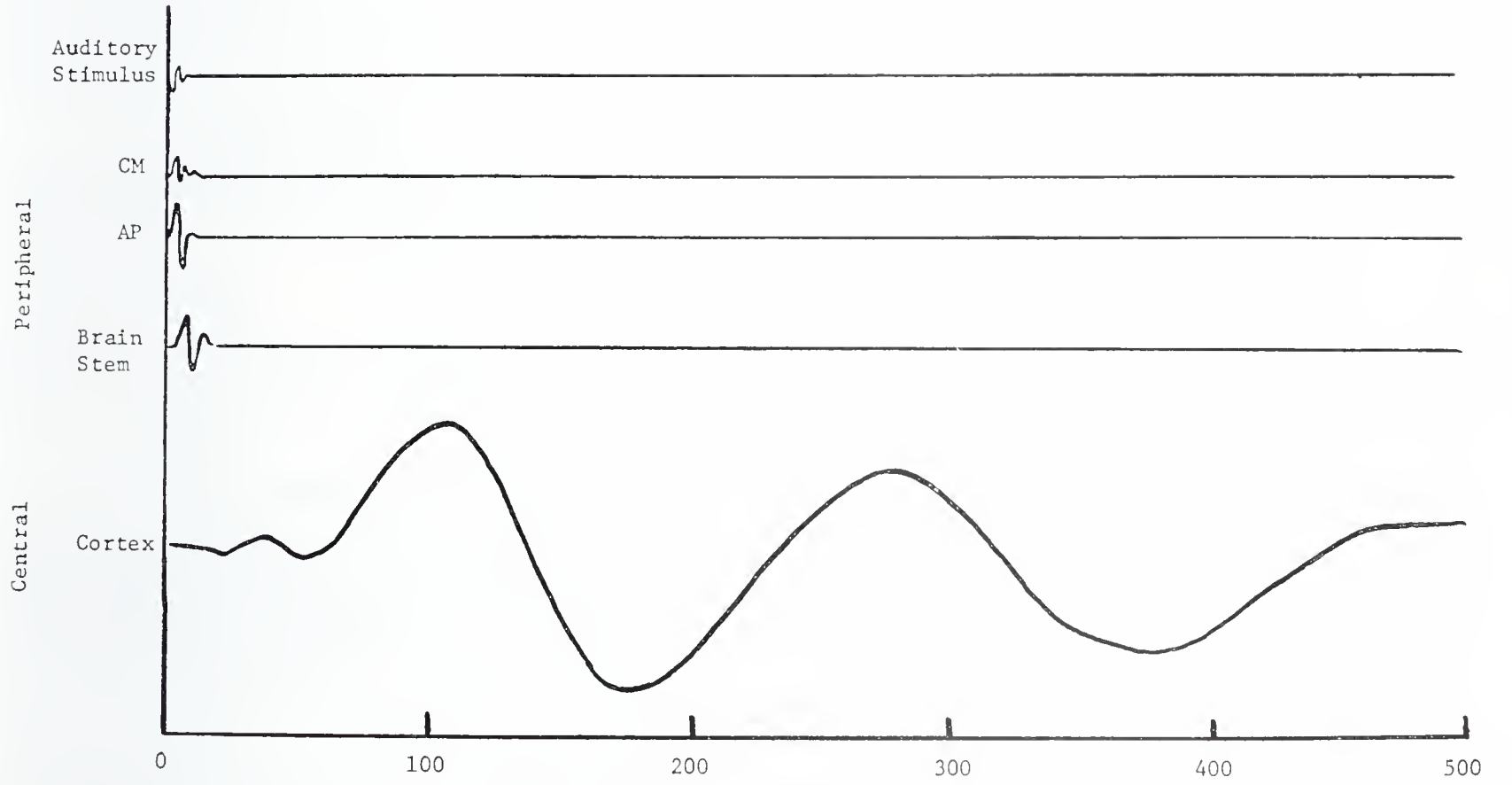


Figure 4

ACKNOWLEDGEMENTS

Acknowledgements are due to my colleagues Dr. D. J. Shepley, Director, Computer Systems; Mr. G. Horny, Supervisor, Scientific Computer Services; Mr. L. Tripp, Scientific Computer Services; Mr. P. Bassett, Scientific Computer Services and Mr. R. Olsen, Scientific Computer Services.

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Multiphasic Screening

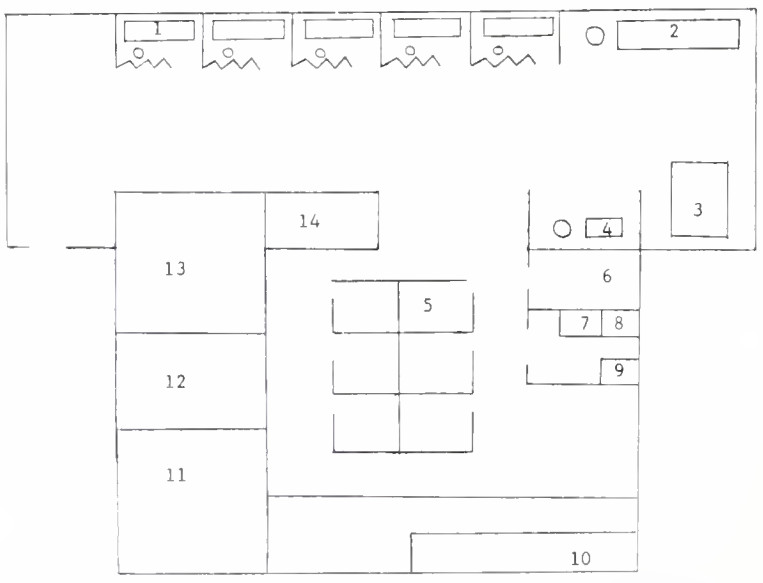
John Anthony, B.A.Sc., M.A.Sc., P.Eng.

The application of engineering methods to medical problems has produced such advances as fully computerized laboratory results and the modern coronary care unit. While some of these advances have produced obvious benefits, the subject of multiphasic screening (mps) has inflamed many passions. In mps many 'normal' patients undergo a battery of multiple biochemical, electronic and physical tests. The ideal purpose of these tests is the attempted early detection of any abnormalities which are the precursor signs of incipient disease. This attempt to catch disease in its early stages is believed valuable both in saving suffering and money if the disease can be stopped or treated in its early stages and more important, to reassure normals of their health. Such programs are meant to supplement or compliment the doctor's role, not supplant it. In addition, mps was designed to catch abnormalities without giving a definitive diagnosis. While certain abnormal values caught in mps would lead to the diagnosis of obvious disease, the usual role of mps is to separate out the normals from the sick and guide the sick to an early diagnosis.

Section I of this paper describes an mps facility while Section II discusses the applications and problems of mps in hospitals and then takes mps one step further, to the possibility of total centralization of multihospital laboratory facilities.

I MEDICOMP

Medicomp, Toronto's first automatic history taking centre accepts patients only on a doctor's referral. The centre claims to do in two hours what would take a doctor or laboratory centre two days, and charges $50.00 per person for a full medical profile which is sent directly to the physician.[1] (Fig. 1)



1. History taking unit
2. Vision Testing
3. Hearing Testing
4. Ocular Tension
5. Changing booth, urine sampling
6. Blood sampling
7. Respiratory Measurements
8. Skin Fold thickness
9. Height & Weight
10. ECG, bp, Pulse
11. Pap smears
12. Thermography
13. Computer
14. Medicomp Personnel

Figure 1

Schematic Diagram of Patient Flow at Medicomp

The patient first stops at a private booth where history taking units programmed for English and Italian are present (German, Portuguese and Spanish will be added). In case of trouble or question, the patient pushes the attendant call button. The branching history-taking program requires only that the patient push the appropriate button next to the desired response to a question.

For Example:

41. Have you ever had a major surgical operation or one for which you were put to sleep with an anaesthetic?

NO
YES

42. Was this operation
ABDOMINAL
BONE
PLASTIC
CHEST
OTHER

43. Etc.

The program executes a thorough interrogation comparable in quality to the famous green book of questions for medical students.[2] The program therefore, questions family history regarding death and family disease, daily activity, education, dwelling conditions, family emotional history and any problems requiring attention. In addition, a number of questions phased in medical terms have a response for "DON'T UNDERSTAND" which, if pushed, explains the terms.

For Example:

104. Have you ever had an intestinal obstruction or an umbilical hernia (not a regular hernia)?
YES
NO
DON'T UNDERSTAND

105. Some hernias occur around the belly button. An intestinal obstruction is a bowel stoppage — not constipation. We'll come to that and regular hernias (ruptures) later. Have you had any?
YES
NO

In addition, the program asks after each problem if:

106. This is why you came to the Doctor
This is an important problem
This is a moderate problem
This is hardly a problem
This is no longer a problem (cured)

If the patient, for example, has professed to have multiple sclerosis, the machine will not accept the "cured" answer, flashes on an error sign to the patient, signifying an improper reply and brings the last statement back for a new response.

The program has separate branches for both sexes. The female program does an excellent job interrogating the patient about her menstrual history, pregnancies and complications, vaginal discharge, contraception and so on. The program also innocently asks the patients who have signified that they use no contraception, if they wish such information from their doctor.

After the program is completed, a final question asks the patient to assess the validity of his own responses. The output correlates the positive and negative responses and prints out a report in English. The output places in an orderly fashion, the reason for the visit (e.g. — CHECK-UP), lists the primary problems, the important problems, all positive responses in a systemic review and and at the bottom, all negative responses. A separate page gives a summary of the patient's reason for visiting, primary problems, important problems, salient information and past problems.

The patient next stops at an instrument which tests visual acuity, colour vision, phoria and stereopsis. Results of each test for this and all other instruments are directly fed to the computer and added to the physicians print-out along with normal values for comparison. The patient moves on to have his ocular tension measured, his hearing tested in all ranges and his voice range measured.

TABLE 1

Technicon Tandem 18 Channel Tests (Serum)

SODIUM	TOTAL BILIRUBIN
POTASSIUM	URIC ACID
CHLORIDE	CALCIUM
CARBON DIOXIDE	INORGANIC PHOSPHATE
UREA NITROGEN	TOTAL PROTEIN
GLUCOSE	ALBUMIN
SGOT	CHOLESTEROL
LDH	CPK
ALKALINE PHOSPHATASE	CREATININE

The next stop is the change facility where the patient dons the usual white garb. Blood is drawn for the 18 channel testing, carried out on the Technicon tandem unit one floor below (tests listed in Table 1) and an additional vacutube is taken for hematology (Table 2). Urine is collected last. In the next room, height, weight, skinfold thickness, vital capacity and $FEC_{1.0}$ are measured. In room 10, the electrocardioanalyzer signals any ECG abnormality so that only the abnormal ECG's are 12 lead ecg's recorded. This instrument operates along the general lines of analysis set out by Milliken[3]. Any abnormal ECG is sent to a cardiologist for interpretation. Rooms 11 and 12 aid in cancer detection in women but the thermograph can also evaluate peripheral vasculature, perform diagnostic studies in skin grafting conditions, burn and frostbite, detect suture thread abscesses and locate placentas. Finally, a routine chest X-Ray is taken in the radiology department and if indicated by the physician, other radiological examinations can be performed.

Hence, Medicomp is not only a computer history taking facility but a full scale laboratory capable of producing a complete health profile. The main use of Medicomp remains screening new patients. While some physicians will prefer to do their own history taking, they may find that a computerized functional enquiry, backed up by a routine laboratory profile will give them a sufficiently good grasp of their patients background from which further probings may begin and allow them to know their patient better than was previously possible. One must therefore consider such facilities not as a displacement of the doctor-patient relationship, but a method to improve it.

The question of ownership of such laboratories may have little interest to the medical student, but it vitally concerns the Canadian pathologist. The Medical Post[4] editorialized that "whenever mps is done, it should be done as an extension of already existing medical services, not in competition with them. Nor should it be promoted as a money-making scheme without regard to its merit". However, Doctor D. Ley[5] felt that the Canadian pathologist is worried that business outside the medical profession is starting large volume automated labs in competition with the pathologists, some of whom have their own private labs. Many people now feel that mps is the area of preventive medicine and not in the province of the pathologist. As for governmental role in the field, Doctor D. MacKay[6] feels that the government's role in any clinical laboratory should be that of standardization of results only and that private competition will make prices competitive.

II MPS APPLICATION TO HOSPITALS

The 18 laboratory tests (listed in Table 2) performed at Medicomp are carried out by a continuous flow multichannel analyzer which theoretically requires only 3 ml of serum. This machine has a down time of only 1 hour per 24 hour period and start-up is only 1½ hours. The unit is standardized by 6 reference standards per hour. Since each sample requires but 1 minute, 54 samples of serum can be run each hour to provide 972 tests per hour or 54 biochemical profiles on either normal persons wishing a general examination or on a hospital population.

In a review of 1869 profiles of patients entering Barnes Hospital, Daughaday *et al*[7] found 15% of the profiles yielded significant abnormalities related to the disease suspected in the physician's initial work-up. These profiles provided the indicated laboratory tests rapidly and efficiently. In 3% of the patients, the profile led to a diagnosis not suspected by the admitting physician. Of 235 profiles showing an elevated blood sugar, 47 led to a new diagnosis of diabetes. In addition, there was the positive value of normal results occuring in their group of predominantly sick patients. Placing the cost of mps on new hospital admissions in perspective, the total cost for the first hospital day is about eight

times the profile's cost. If prompt use of a 12 or 18 channel chemical profile saves one hospital day for one of eight patients, it could be justified on this one criterion alone.

TABLE 2

URINALYSIS:

PH	6.0
GLUC	NEG.
KET	NEG.
BLOOD	NEG.
PROT	NEG.

URINE MICROSCOPIC:

WBC	0-5/H.P.F.
RBC	0-1/H.P.F.
CASTS	ABSENT
CRYS	ABSENT
BACT	ABSENT OR FEW
OTHER ELEM.	ABSENT

HAEMATOLOGY:

		VALUE	NORMAL RANGE
RBC	M/CMM	5.2	4.6 – 6.2
WBC	T/CMM	8.5	4.8 – 10.8
HGB	GM	16.8	14.0 – 18.0
HCT	%	16.8	42 – 52
MCV	CU MIC	90.4	82.0 – 97.0
MCH	MMGM	32.3 **	27.0 – 31.0
MCHC	%	35.8	32.0 – 36.0

BLOOD MICROSCOPIC:

RED CELLS	SHAPE -- NORMOCYTIC
	COLOR -- NORMOCHROMIC
PLATELETS	ADEQUATE

DIFFERENTIAL:

POLYS	36 %
BANDS	0 %
LYMPHS	23 %
MONOS	1 %
EOSIN	0 %
BASO	2 %
COMMENTS	NO APPARENT ABNORMALITIES

-- = NO DATA FOR TEST
X = UNABLE TO MEASURE
* = SUSPICIOUS VALUE
** = ABNORMAL VALUE

The problems of using such a scheme are many. Which tests to use, which chemical method for that selected test, what time to do the test, etc., must be carefully pondered. The choice of tests by the Technicon Corp., manufacturers of the 18-channel unit, appears based mainly on the availability of easy chemical methods. The problem with this selection is that the physician had no say in which battery of tests he considered the most valuable for his patients. As Doctor A. Pollard[8] argues, there must be an arrangement whereby the users of a facility determine how that facility works for them. While the determination of which chemical method should be used for each test should be left to the mps staff, the hospital physicians must have the deciding voice in which series of tests are to be run. The chemistry used in each separate test must be considered very carefully but such is beyond this paper's scope. There are, however, some procedures used in the Technicon equipment which could be questioned.

Blood for testing is presently taken at a non-specific time. As Doctor W. Forbath[9] has pointed out, the inorganic phosphate drops precipitately from 'normal fasting' after glucose is ingested so that a random serum phosphate is as meaningless as a random blood sugar. Hence a specific time must be found which optimizes the tests selected. Most important though, is the need to decide what numerical value constitutes an abnormal reading. A study is necessary to determine which range of values for each test is normal for the general population. However, the extremities of the range of normal merge with the extremities of the range of abnormal and it is in these ranges of values the normals get labelled as false-positives.

The subject of false-positive results requires investigation of several areas; the percentage of false-positive results obtained during mps, the cost involved in disproving false-positive results and the time involved in reassuring patients, and the true ratio of false-positive results to the detection of serious disease. In fact, the frequency of false-positive results varies with the diagnosis and tests used and the frequency of false-positive results should compare favourably with a comparable traditional patient work-up by the physician. Some work has been done, however, to place a rational value on mps.

Doctor David Lawee[10], in a random series of 1,000 serum calciums and 1,000 phosphorus in TGH's outpatient department found only one clinically significant yield (post thyroidectomy hypoparathyroidism), one case of milk-alkali syndrome and one case of known renal acidosis at a cost of $10,000. The main problem, however, is that no organized attempt has been made to catalogue or assess the effects on patients on mps programs. As Doctor Murray Young[11] puts it, the problem is one of diagnosing non-disease, that is, the diagnosis of the disease which is there because the label is there while the disease itself is not.

Doctor Young points out that "screening" for a low incidence of disease must always, with mathematical predictability for given situations, label cases of non-disease at a level much higher than the population incidence for the true disease. Hence the patient suffers from the diagnosis and not the disease. The solution to this problem is retesting each laboratory positive patient so that most "label-positives" are re-labelled negatives (assuming that this is a standardized test). Again, Doctor Young's worry is that little has been found out about the benefits or harms accruing to the patients who receive additional diagnostic labels; little has been found out about the harm, inconvenience and expense inherited by patients recalled but not relabelled. These problems appear to be valid only when the supervised patient is either informed that he has an abnormal value or is sent back to the mps centre. If the patient, however, has been sent to the mps centre by his physician, and if the results are sent only to the physician, then the physician is only aware of possible underlying conditions and exercises his

clinical judgement knowing that there exists such things as false positives and machine error.

In a society of automated medicine the physician must exercise his clinical judgement tempered by laboratory results. But knowing the degree of error inherently possible in laboratory results, he must exercise his clinical judgement above all.

Cost-Benefit studies are unfortunately not possible in medicine. For any diagnostic procedure there is no way of measuring all the benefits, such as the extended years of productive life from an early cure of a true-positive test or the relief from anxiety from a proved negative one. Nor can we measure the costs for anxiety or time lost from usual activities for diagnostic procedures that ultimately prove the absence of a suspected condition.

Once decisions have been made between all concerned with mps in one hospital, it becomes reasonable to question the application of mps to the neighbouring hospitals. Because the mps biochemical units can process samples both quickly and efficiently, closely located hospitals could use a single facility at lower cost. The city's hospitals are already loosely bound by the In-Common Laboratory which performs tests normally too expensive for each individual hospital because of low volume demand for these tests. This In-Common Laboratory is the logical initial step towards a totally centralized laboratory facility. The centralization could best tie together the closely situated Toronto General Hospital, New Mount Sinai Hospital, Hospital for Sick Children and Women's College Hospital. Such a possibility, on the surface at least, appears quite likely and would provide standardization results and a 24-hour STAT service if set up as outlined below:

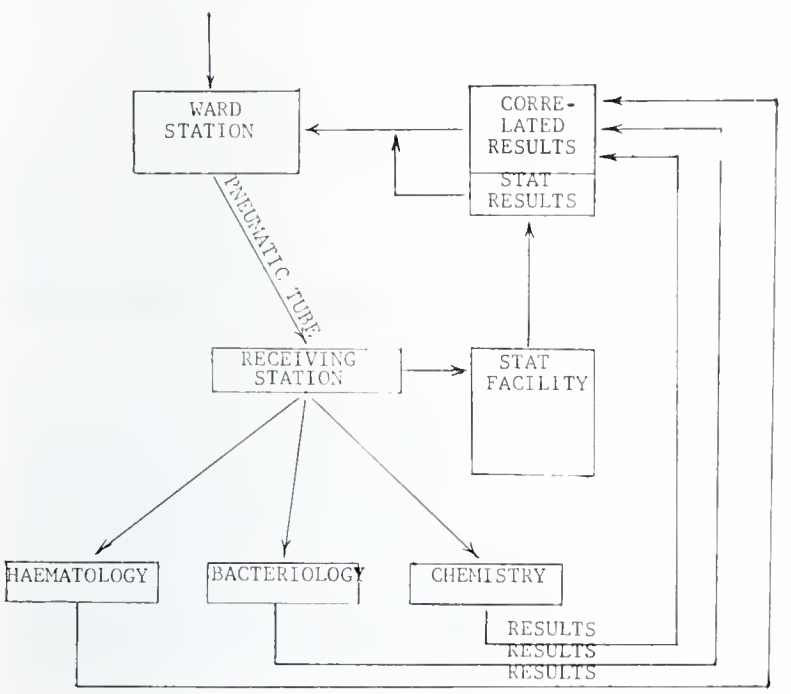


Figure 2
Flow Diagram of an In-Common Laboratory

Figure 2 sketches the information system applicable to one hospital with its own laboratory or to several hospitals serviced by a central laboratory facility. Ideal circumstances require quick sample delivery to the laboratory. A pneumatic tube system similar to that in use in Hanover, Germany could be utilized. The receiving station segregates samples and delivers them to each division: Hematology, Bacteriology-Virology and Clinical Chemistry-Biochemistry. Results from all divisions are immediately sent to file where they are collated. A summary sheet is transmitted to the ward when ready or earlier if only partial results are desired. Such a data facility is already in partial use at The Hospital for Sick Children.

A separate STAT facility could be arranged for quick blood gases, etc. and these results instantly transmitted to the ward. By using such an in-common facility the hospitals would be ensured of continued standardized service.

No study has yet been carried out to assess the possible financial savings of such a laboratory or has any study assessed the dangers of setting up such a facility. However, such a facility is presently possible using available technology.

SUMMARY

A multiphasic screening centre is described and the applications of multiphasic screening to hospitals discussed. The problems with multiphasic screening are:

(1) the cost;
(2) the physician's role in deciding the tests used;
(3) the optimal time for sera sampling;
(4) the problem of false-positives;
(5) the possibility of linking city hospitals through a common laboratory facility.

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*Implant Materials And Their Use In Orthopaedic Surgery**

W. J. Peters, Ph.D.

METALLIC IMPLANTS

The first known use of metallic implants introduced into the human body for the treatment of disease dates back to 2700 B.C., when the Ancient Chinese used a form of treatment known as acupuncture[1]. This was not a method of gaining structural stability, but consisted of inserting fine needles of silver or gold into tissues at the site of pain or at a distant site. The needles were then allowed to remain in place from a few minutes to several days, with varying effect. Various forms of this treatment are still utilized in some parts of the world.

Very little progress was made in the use of metal implants for a period of many hundreds of years, until Lusitanus, in 1560, devised a gold plate for the repair of cleft palate defects.[2] The following years evoked great turmoil over the use of internal fixation. In the early 1770's, surgeons began to use various types of metal wires to secure fracture fragments. However, during this pre-microbiological era, surgical procedures were frequently complicated by the development of gangrene which was observed to "kill patients like a pistol shot".[1] Many surgeons believed that the implant materials were directly responsible for this infection. Pancoast, in his famous treatise on operative surgery (1844)[3] finally concluded that metal implants "should not be used in fractures, as they cause bone necrosis".

Malgaigne, in 1847, proposed a compromise to the opposing views of open versus closed reduction[4]. He introduced an external-internal fixation unit for fractures of the knee and elbow, in which adjustable hooks were attached to a clamp. The hooks went through the skin into the bone fragments and the external clamp was tightened using a special wrench. Although this particular device had only short-lived success, modifications of this procedure, e.g. Roger-Anderson apparatus, are currently employed in orthopaedics.

In the second half of the Nineteenth century, two extremely significant developments pushed orthopaedic surgery toward the modern era. In 1860, Lister recognized that infections were caused by micro-organisms and advocated antiseptic precautions in surgery.[5] In 1895, Roentgen's monumental discovery[6] enabled orthopaedic surgeons to view reduction being obtained, and precipitated a revival of interest in open reduction and internal fixation of fractures.

In 1886, Hansman devised the first practical metal bone plates and screws.[7] The screws and one end of the plate were left protruding from the wound, and could subsequently be easily removed using a watch key. Lane further developed the concept of plates and screws and introduced a rigid plate which could be permanently left inside the wound[8] (Fig. 1). His greatest contribution however, was in his insistence upon rigid asepsis which was later known as the "Lane no-touch technique". He claimed never to have observed "rarefying osteitis" in any of his patients, and stated emphatically "Rarefying osteitis in plain English means dirty surgery and is a useful term to cover surgical incompetence"[1].

In the following years, with greater insistence upon aseptic precautions, significant advances were made in the use of internal devices for the fixation of open fractures. Sherman observed that the Lane plate, which was made of tool steel or crucible steel, was too brittle to withstand bending or twisting strains. In 1912, after three years of research, he developed a new steel alloy, which contained vanadium and chromium and lower levels of carbon[9] (Fig. 1). Bone plates made of this vanadium steel were shown to be about three times stronger than other forms of steel. He subsequently used self-tapping vanadium steel bone screws and recommended laterally curved plates which introduced less metal into the wound (Fig. 1).

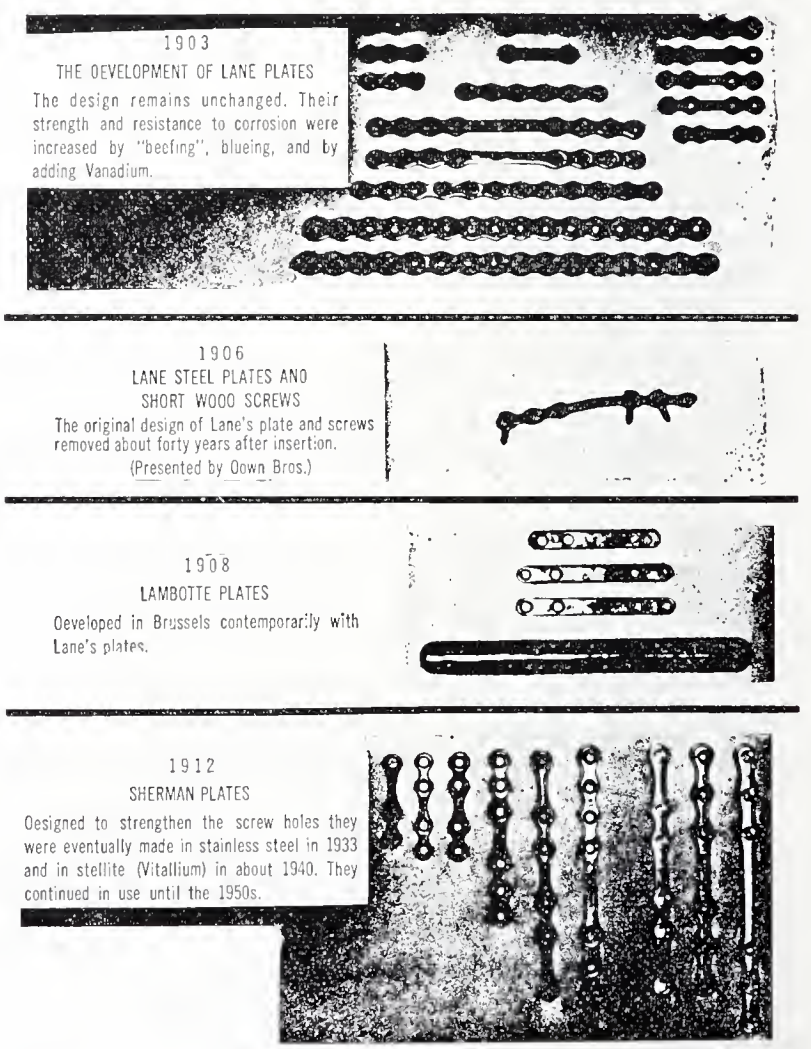
1903
THE DEVELOPMENT OF LANE PLATES
The design remains unchanged. Their strength and resistance to corrosion were increased by "beefing", blueing, and by adding Vanadium.
1906
LANE STEEL PLATES AND SHORT WOOD SCREWS
The original design of Lane's plate and screws removed about forty years after insertion. (Presented by Down Bros.)
1908
LAMBOTTE PLATES
Developed in Brussels contemporarily with Lane's plates.
1912
SHERMAN PLATES
Designed to strengthen the screw holes they were eventually made in stainless steel in 1933 and in stellite (Vitallium) in about 1940. They continued in use until the 1950s.

Figure 1. The development of metal bone plates and screws.

In 1913, Hey-Groves[10] conducted a study of tissue tolerance to various metals and then advocated the use of nickel-plated steel. From 1912 to 1914, numerous

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workers began to use metallic bands to secure fractures. Increasing experimentation led to tremendous controversy, because metal bands which were left in place produced circumferential bone notching that frequently resulted in another fracture. This problem was solved in 1913 by Parham and Martin who developed a removable band[11].

The original techniques of intramedullary nailing were first developed by Hey-Groves in 1908, for fractures of the shaft of long bones and of the neck of the femur[12]. He used various types of material, including beef bone, ivory pegs, and several different metal alloys (Fig. 2). Many problems developed — the organic materials frequently loosened and failed, and the steel implants often corroded. As more workers experimented with a wider variety of new metals, adverse chemical tissue reactions to these materials became increasingly apparent. In 1927, Lambotte[1] described the "electrolytic phenomena" of certain metallic appliances in the body, and workers began to experiment with other metal alloys.

In 1931, with the development of stainless steel, Smith-Peterson re-introduced the procedure of hip nailing[13]. In 1936, Rush and Rush introduced intramedullary pins with a curved extraction hook (Fig. 2), facilitating subsequent easy removal.

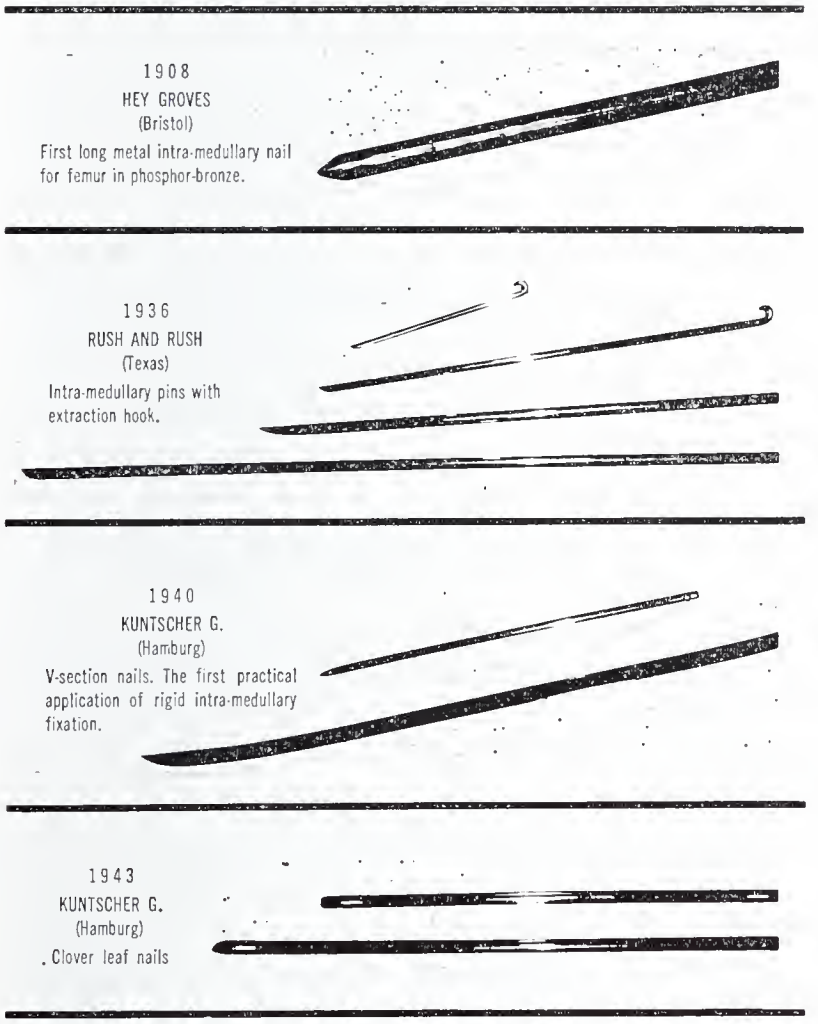

Figure 2. The development of intramedullary fixation devices.

In the following year, surgeons became increasingly aware of the mechanical forces acting at different fracture sites and a wide variety of implant designs were created. Although intramedullary internal fixation had been attempted previously, Kuntscher in 1940 became the first to successfully develop this technique[14]. He used "V" shaped nails of stainless steel which were driven down the medullary cavity of a fractured bone. In 1943, he changed the cross-sectional design to a "clover leaf" to increase stability by filling the medullary canal (Fig. 2), thus, the mechanical forces of angulation, lateral displacement, and torque were better controlled. Motion of the adjacent joints could be initiated immediately and muscle atrophy and stiffness were minimized. In some fractures of the femur, union was so rapid that patients could walk without additional fixation in two to three weeks. Although Kuntscher originally recommended his method for fractures of all long bones, intramedullary nailing of thousands of fractures over the following decade, showed that except for fractures of the femur and other selected cases, most fractures could be better treated by other measures.[15]

The modern era of metallic implants has been characterized by the development of more acceptable alloys and by advances in the mechanical engineering of prosthetic appliances. In 1936, a new alloy of cobalt, chromium and molybdenum (Vitallium) was shown to be essentially inert in body fluids[16]. Newer minimally - reactive stainless steels have also been developed. With the development of image intensification in the 1950's, reduction and internal fixation of fractures could be readily observed without subjecting patients to high doses of radiation. Modern implants have now been improved to the point where they are used with almost complete confidence by the orthopaedic profession.

During the past decade, Müller and his associates in Switzerland[17] have developed numerous highly refined techniques for applying compression devices to rigidly fixed and perfectly reduced shaft fractures. The underlying principle of this procedure is that rigid fixation of bone fragments under compression increases the area of contact and minimizes shearing and torsional forces. There is no resorption of fragments, but primary bony union occurs in the absence of visible endosteal or parosteal callus. Although the Swiss group have carefully documented over 14,000 operative cases using compression plating[17] and have demonstrated many advantages of this technique, it remains to be proven that compression in itself accelerates normal fracture healing in cortical bone. Research workers however, are currently studying this relatively new concept of internal fixation.

CEMENTING SUBSTANCES

Concurrent with the search for the ideal material for metallic implants, research workers have in recent years explored the possibilities of cementing substances for use in orthopaedic surgery. Three potential uses for bone cements are: a) to function as space fillers in cancellous bone defects, b) to stabilize fractures, and c) to secure

metal implants to bone. Each of these situations requires a substance with specific characteristic properties.

a) *Cementing substances to fill bone defects*

The ideal material for use as a space-occupying substance in bone should: i) be easily sterilized, ii) have the required physical properties of strength, elasticity and hardness, iii) be easily shaped prior to setting, and iv) be biologically inert. One of the first materials tested in this role was plaster of Paris, which, when mixed with water, becomes $CaSO_4 .2H_2O$ or gypsum. Since the initial investigations in this area by Trendelenburg in 1892, literally hundreds of workers have attempted to use this substance in bone defects, with only limited success[18] The largest obstacle in the use of plaster of Paris is the effect of blood and tissue fluid on its setting. Under selected conditions, however, this material has been observed to be resorbed rapidly with osseous regeneration.

During the past decade, extensive research has been done on polymeric adhesive materials, such as the cyanoacrylates, polyurethane, and various epoxyresins (for a review see refs. 19 and 20). Although these polymers were originally thought to be chemically stable and biologically inert, subsequent investigations have, in many instances, raised serious doubts about their stability and toxicology[19, 21].

During the past few years, implantation research has been directed towards the development of a self-locking implant — either a) hydrophilic materials capable of expansion on setting or b) porous substances, into which bone would grow to provide stability. Many hydrophilic acrylate polymers ("Hydrons" e.g. 2-hydroxyethyl methacrylate) appear to possess a self-locking capacity, by virtue of their ability to absorb fluid with concomitant swelling[21]. Hydrons of high mechanical strength are obtained if their polymerization is carried out under conditions which provide a water content of 45%. These gels can, however, be polymerized at a lower water content (eg. 25%), to provide a solid partially pre-swollen material, which on implantation swells to provide a self-locking condition. The hardness or resiliency of these gels can be controlled by the proportion of cross-linking agent used in polymerization. Some of these compounds appear to be biocompatible and will undoubtedly be developed further for use in orthopaedic surgery, possibly for the purpose of replacing focal defects in articular cartilage. A major disadvantage is their friability or lack of tolerance for major stress — a problem which may be solved by further research on their chemical structure.

Polyvinyl and acrylate-amide "sponges" were studied initially, as potential porous implants, but their poor physical properties reportedly limited their use[22]. Recently, as an extension of the space age interest in heat-resistant substances, the search for a stronger material led to the development of porous ceramic substances[23]. Solid wedges and spacers composed of ceramic materials are currently used in osteotomy and limb lengthening procedures. Since the initiation of ceramic implant programs in 1968, experimental applications of these materials have included total and partial hips and knees, temporomandibular condyles, mandible implants and cranial defect repair procedures. More recent experimentation in this field has led to the development of Cerosium[23], a porous ceramic substance impregnated with an epoxyresin, which was formulated to have a pore structure and physical properties similar to bone[24]. This material will most certainly have further applications in clinical orthopaedic surgery.

Other organic materials which have been used extensively in orthopaedic surgery are preparations of silicone rubber (Silastic). Silastic was originally introduced in 1966, as a pliable, one-piece, hinge type, intramedullary prosthesis for metacarpophalangeal and interphalangeal joints. Following implantation, the prosthetic stem glides freely within the intramedullary canal, or becomes totally or partially bound by a supportive fibrous joint capsule. Subsequent research has led to the development of radial and ulnar head, scaphoid, lunate, trapezium, and other prostheses. Recently, a dacron mesh has been applied to the external surface of the silicone finger joint prostheses. Fibrous tissue rapidly infiltrates this dacron mesh to provide greater fixation of the prosthesis.

b) *Stabilization of fractures*

Many cementing substances have been tested in an effort to provide stability in certain pathological and comminuted fractures of long bones. The ideal substance for this purpose should: i) form a firm adhesion with bony surfaces, ii) not impede the normal fracture healing process, and iii) be subsequently resorbed without deleterious effect. Many of the previously mentioned polymeric compounds have been tested in this capacity, generally with poor results. One such material which appeared initially to satisfy the requirements of "nontoxic bone glue" was Ostamer (polyurethane)[25]. This material was used extensively over a two year period in the United States, but its use was subsequently discontinued because it failed to facilitate fracture union and it produced a variety of side effects in susceptible patients.

Very little progress has been made in the stabilization of fractures using cementing substances. Newer adhesives are undergoing clinical trials but none of these have yet reached the stage of widespread clinical application.

c) *Cementing substances to secure prostheses*

The main area in which clinical success with cements has been achieved is in the adhesion of orthopaedic prostheses. Total hip prostheses are probably the most extensively studied internal prosthesis in orthopaedic surgery. The concept of replacing a femoral head with a prosthesis was initially developed by Judet (using an acrylate plastic) in the late 1930's, and subsequently modified by Thompson, Moore, and others (using steel and metal alloys)[26]. Acetabular cups of Teflon (polytetrafluoroethylene), Teflon derivatives (Fluorosint), and

high molecular weight polyethylene have been used. At present, the most suitable materials for an artificial hip joint are vitallium or stainless steel for the prosthetic head, and high density polyethylene for the acetabular cup[26, 27, 28].

The basic concept of total hip arthroplasty involves resection of the femoral head and replacement with a long-stemmed prosthesis, which is mechanically fitted into the intramedullary canal of the upper end of the femur. The acetabulum is also replaced with a socket of polyethylene. However, under certain conditions, such as the presence of malfunctioning hip adductors or osteoporotic femoral shafts, loosening of the mechanical bond may occur, with subsequent restriction of motion and joint pain[28]. Mechanical failure was thought to result from the abrupt transference of stress from the rigid metal implant to the surrounding elastic bone tissue.

In the early 1950's, surgeons began searching for a cementing substance with elastic properties intermediate between metal and bone, which could be interposed between the two surfaces. In 1958, on the advice of Smith, Charnley began to use methyl methacrylate for this purpose[29].

Kiaer had previously used this acrylate polymer as early as 1941 in the fixation of the Judet femoral head prosthesis[30] but his early trials invariably met with failure because of the mechanical disadvantage inherent in the short-stemmed Judet prosthesis. Other workers[31] also used methyl methacrylate for femoral head replacements, but did not insert it into the medullary canal.

Methyl methacrylate is a polymeric self curing acrylate cement which acts as a mechanical filler without actual adhesive properties[28]. It's physical setting is facilitated by mixing pre-polymerized acrylate, the monomeric form, and a chemical activator, which undergo an exothermic reaction to harden the polymer into a solid matrix in 5 - 10 min.

Immediately following mixing, the cement is forced down the femoral medullary canal. Insertion of the tapered prosthetic stem subsequently forces the cement into the cancellous lining of the marrow space to produce a cement thickness of 2 - 4 mm. The prosthetic stem and the hardened cement sheath subsequently function as a single unit. Weight is initially transmitted through thousands of bony trabeculae in the endosteal femoral surface and subsequently through newly formed fibrocartillage. Mechanical tests have shown a 200 fold improvement in load-bearing capacity of the prosthesis compared to a similar situation without cement[28]. Polyethylene acetabular cups are also firmly fixed with the acrylate cement.

To date, Charnley has performed more than 5,500 total hip arthroplasties using methyl methacrylate with overall excellent results. Many patients with atrophy of the femoral cortex have demonstrated hypertrophy following polyacrylate implantation, probably due to the improved physiological response to mechanical stress. There are, however, two disadvantages associated with the use of this cement: a) heat production which causes some degree of bone death around the prosthetic stem, and b) a mild cytotoxicity associated with the residual acrylate monomer in the set cement[28]. In spite of these disadvantages, methyl methacrylate has proven to be the most successful cementing substance utilized to date in total hip arthroplasties, and will undoubtedly be applied to other prosthetic replacement procedures.

The use of methyl methacrylate has not been confined strictly to orthopaedic surgery. Shapiro[28], in 1969, collected 480 references on the use of this acrylate polymer in other surgical specialties. It has been used in plastic surgery for reconstruction of the nose and orbital region, in dental surgery for securing both internal and external prostheses, in cranial surgery to fill skull defects and to invest cranial aneurysms where standard techniques are not possible, in opthalmic surgery for contact lenses, intra-ocular lenses, and the repair of lacrimal ducts, and in otology to replace ossicles.

FURTHER DEVELOPMENTS IN BONE CEMENTS

In 1968, Dr. D. C. Smith, Professor of Dental Material Science at the University of Toronto, described the preparation and mechanical properties of a new dental cement — zinc polyacrylate (PAZ) — composed of polyacrylate acid (Fig. 3) and a zinc oxide preparation[32]. Setting of the cement was suggested to be due to a chemical bond between Zn^{+2} ions and four adjacent carboxyl groups in the polyacrylic acid molecule[20], to produce a solid gel-like structure (Fig. 4). In addition to forming a strong mechanical bond, PAZ has the unique property of forming a tenacious chemical bond with suitably calcified surfaces through the chelation of calcium ions by free carboxyl groups in the acrylate polymer[33] (Fig. 4). PAZ was further shown to form a direct chemical bond with stainless steel and various other metals, facilitating its use as an adherent of implant materials to calcified surfaces[34]. A number of different chemical preparations of this polycarboxylate cement are currently being employed under a variety of dental clinical conditions.

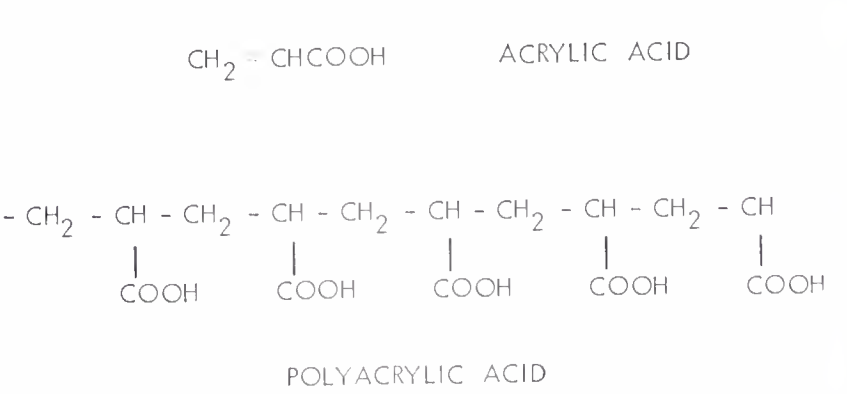

Figure 3. Chemical structure of the monomer and polymer of acrylic acid.

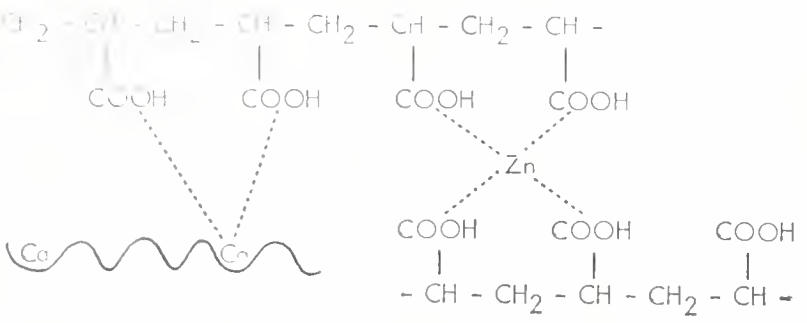

Figure 4. Postulated bonding mechanisms of polyacrylic acid to calcium and zinc ions.

Because of the unique binding properties of PAZ, and because in a preliminary clinical trial, it appeared to be resorbed from bone without deleterious effect[34], this polymer has been investigated as a potential implant material in orthopaedic surgery[35]. During the past two years, in association with Dr. D. C. Smith, we[35] have been conducting experiments on the chemical, physical, and toxicological properties of PAZ as a bone cement.

PAZ, prepared with radioactive ^{65}Zn was first assessed under *in vitro* conditions to measure and reduce the solubility of the cement. Non-radioactive PAZ was subsequently implanted subcutaneously, into cortical bone defects, and into osteotomy sites of a series of animals, which were sacrificed at two monthly intervals over the ensuing 12 months. Gross, morphological, and histological examination of these animals showed no evidence of a chronic inflammatory response or toxic reaction during the one year study period.

In another set of experiments, radioactive PAZ was implanted into a series of animals which were later sacrificed and analyzed. The result of these experiments revealed that more than 99% of the radioactivity was confined to the site of implantation after 1 year. PAZ was thus shown to be totally insoluble and non-toxic under *in vivo* conditions.

PAZ appeared to possess many advantages as a potential implant material in orthopaedic surgery. Unlike methyl methacrylate, its setting is not associated with a biologically destructive exothermic reaction. It has a higher compression and tensile strength than many other cements, and these properties are subsequently improved by storage in water[34]. Experiments are currently in progress to increase the binding properties of PAZ using different chemical preparations of the material. Experiments are also being conducted on the use of PAZ to secure prostheses to amputated limbs in experimental animals. Further investigation of polyacrylic acid and of various other biopolymers will undoubtedly lead to their ultimate use in many facets of orthopaedic surgery.

OBSTACLES IN THE DEVELOPMENT OF IMPLANT MATERIALS

The development and ultimate successful use of implant materials in orthopaedic surgery involves an integration of basic science and clinical medicine. Any material implanted into the body is continually subjected to numerous mechanical, chemical and metabolic forces. Over many years, the substance is partially degraded, into potentially toxic constituents. Any foreign material invariably causes some degree of chronic inflammation.

Before a material has been implanted into the body, the possibility of long-term malignant transformation must be extremely carefully evaluated. At present, there is little uniform agreement of the criteria of carcinogenicity. In the United States, materials must be accepted by the Federal Food and Drug Administration, whose criteria are presently ill defined. One problem with animal evaluation of implant materials is that the species in which a test is conducted may have a different susceptibility to malignant transformation than a human. Teflon (polytetrafluoroethylene), for example, was previously shown to be non-carcinogenic in animal implantation experiments and was therefore used extensively in orthopaedic surgery. Subsequently, it proved to be "one of the most irritating materials ever used in surgery, producing caseating granulomata, sterile pus, and bone erosion"[28]. Conversely methyl methacrylate was shown to produce malignant changes after implantation in rats[36], but has failed to be carcinogenic after 20 years in human subjects[5].

While the general lack of agreement on standards of implant quality and toxicity has resulted in the use of certain toxic materials in human subjects, it has conversely prevented the use of certain apparently non-toxic potentially advantageous substances. Methyl methacrylate, for example, which is being used very successfully and extensively in Europe and the United Kingdom has not (at the time of writing) been released by the Food and Drug Administration for use in the United States. This problem of induced toxicity must clearly be defined if progress in surgery is to be made through implantation research.

Current emphasis on the development of cementing substances is directed towards materials which, in addition to having the required physical and chemical properties, would be totally metabolized in the body to non-toxic products. Methyl methacrylate, for example, which is only slightly degraded *in vivo*, appears to undergo two oxidation reactions to yield pyruvate, which is subsequently metabolized completely to carbon dioxide and water[37]. Many experiments are currently being conducted on naturally-occurring animal proteins, which could be chemically hardened into implant substances. Continued basic and clinical research in the study of bio-polymers and other organic cementing substances will undoubtedly lead to the development of the ideal non-toxic biodegradable implant material for use in orthopaedic surgery.

SUMMARY

A review is presented of the historical development of metallic implant materials and cementing substances used

in orthopaedic surgery. Special emphasis is placed on recent advances in the field of organic polymer adhesive materials and their biological advantages as implant substances. The current status and future goals of orthopaedic implantation research are described,

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Engineering And Medicine: Partners In Applied Science

H. Schipper, B.A. Sc., 7T2

It is easy to be both an engineer and a medical doctor. In fact, it may well be easier for an engineer to function effectively in clinical medicine than it is for a non-engineer.

Ten years ago such a statement probably would not have rated enough serious consideration to be termed heretic. But the explosion of both knowledge and technology, coupled with increasing time and cost demands imposed upon current medicine make such statements, within the short span of a decade, seem almost trite. The general public is already well attuned to heart-lung machines and artificial kidneys, both relatively primitive products of the engineering-medicine symbiosis. Doctors as well are beginning to think in terms of health status indices, clinical efficiency, and modeling approaches to medical pathology. The engineer, for his part, is becoming increasingly absorbed in the design and implementation of automated systems for information retrieval and laboratory processing.

But the real symbiosis, for it is a shared growth, is more profound than rather simpler machines and borrowed concepts, for both medicine and engineering, in their intellective roots and practical approaches, share very common philosophies. Simply stated, both doctors and engineers think the same way about problems which, at their essential core, are the same.

MD — Bachelor of Applied Biological Science

Since before Hippocrates the object of medicine has been and continues to be the application of known biological facts to the solution of medical problems. The understanding of every malady, and the therapy prescribed for every illness has had its basis in some body of fact, however primitive. This is as true of bloodletting as practised in the middle ages, as it is of the cardio-pulmonary support systems of today.

Equally, in designing the American moon missions, the project engineers utilized basic concepts of physics which were outlined quite completely by Newton almost 500 years ago. All that was lacking until recently were fuels with a high enough energy to weight ratio, and computers to manipulate all the numbers fast enough.

Hence, both engineering and medicine use theory and basic science as direct precursors to application. In fact, the doctor is every bit as much a Bachelor of Applied Biology as the professional engineer is a Bachelor of Applied Science. The suffix M.D. is largely a peon of history, not to speak of public hope and the will to live. Those who think otherwise are reminded that one poorly placed rivet in a suspension bridge can kill or maim more people than one poorly placed physician. In both disciplines, mission effectiveness is a clearcut function of reasoned application of sound basic principles. In medicine our therapeutics are best when we understand the mechanism of disease. In engineering, the concepts most fruitful in development and application are those that are firmly established in sound basic science.

What about all the diseases we don't understand? In this respect as well, doctors and engineers are of the same school. We stretch science and our body of basic knowledge as far as possible, seeking to glean implications for the unknown from the corpus of the known. In the end, we attempt by trial and error, "empirically" as the engineer would say, and we do things because they seem to work.

No one knows why aspirin works, yet its effects in alleviating pain, soothing the arthritic's inflamed joints, and lowering burdensome temperature, by the force of effect alone justify widespread application.

Similarly, many of the formulae used in the design of modern aircraft though they are dimensionally incorrect and virtual mental figments of an imaginative mathematician when confronted with a stack of data, are used because of their proven effectiveness.

Hence, both engineers and doctors supplement science with seasoned empiricism. We do things because they work. Regretfully often they are the minimal best that we can provide.

The Promise of Divergence

We have thus far seen that doctors and engineers face problems which are highly similar in concept. Yet, on the face of things, be it in a doctor's office or at the drafting board the problems seem miles apart. However, all that is really different are the circumstances and preconditions for experiment and solution.

There are three basic differences.

The first is reproducibility. Every nail in a box can be made as identical as cost and care will permit. No two humans, even homozygous twins, are quite alike. Thus the engineer can expect to build a machine which will bend or modify his nails in a precise manner within clearly pre-determined tolerances. Would that physicians could manage similar manipulations with their seemingly similar patients.

There is yet a second implication of this massive difference in reproducibility. Statistical interpretation of data in medicine must of necessity be far less stringent and the bounds for validity far broader than those in engineering or physics. Biology imposes limits which could not be tolerated in the physical sciences.

In no small measure this problem contributes to many of the diagnostic and therapeutic controversies which

both plague and invigorate modern medicine. Poorly conceived experimentation is another major contributor.

The second difference concerns the problem of simulation. Long ago engineers learned to build model bridges before building real ones. They knew that if there were forces which they had neglected in their calculations, their effects would be reproduced *to scale* on a scale model. This particular tool, called scaling, has made possible everything from skycrapers to bridges, motors to supersonic aircraft.

Biological researchers have no such scalable models. We can only infer from far less than identical models. Immunologists must derive much basic information from small animals, knowing full well that there are fundamental differences between the experimental animal and the human recipient of such basic research. Fortunately, every so often nature provides a link in the form of a disease, for example, like the immune deficiencies, which permit some more direct, but still not synonymous comparisons.

The third difference may well prove of greater significance than the others. What will only be alluded to presently in order to explore it more fully later is the problem of isolation of variables. Physical scientists are pretty well able to identify the parameters incipient upon a situation and isolate them, albeit laboriously, in order to examine them in the classical method. With patience and determination all variables save one can be identified and fixed, so as to examine the effect a change in one parameter has on the system as a whole.

Such can seldom if ever be done in the biological milieu. The number of identifiable parameters, many beyond the control of the investigator, is far too great to be rigorously controlled. Furthermore, many of the forces which profoundly affect biological systems are microscopically subtle, often defying identification.

Biological materials, from cells to complete organisms are living materials, whose requisites for viability impose considerable limitation on the investigator's approaches.

There are ethical questions as well, which affect both the physical and biological sciences. There will probably be little argument offered to the contention that medicine is more frequently and pressingly faced with ethical considerations than are the physical sciences.

Finally, a corollary of the three basic differences. It is easy to use an iterative, return and try again system in the physical sciences. It is far less possible to do so in the bio-sciences. For one thing, it is quite impossible to undo something to a biological system. There is no such thing as replacing an appendix. When a doctor changes a patient's medication, he often cannot know whether the changes he observes later are in response to the former or latter drug, or both, or if they are the natural course of the disease process. The problem is both perplexing and frustrating.

Hence the bio-sciences and engineering have evolved methods and approaches particular to their own unique circumstances and pre-conditions. Our root problems are still similar though, and it would seem that by careful open-minded scrutiny of our co-professional's methods we may well be able to effectively modify and advance our own techniques. Our paths have been separate long enough that the ideas are clearly divergent. But our problem types are common enough that useful hybridization will develop.

Engineering for Doctors

Engineers are concerned with efficiency and making things go. They want to put things together so they work. Sometimes understanding their inventions must wait until later.

Aside from simple mechanical extensions of human effort, valuable as they may be, there are three areas in particular of the engineering milieu that medical personnel are beginning to assimilate.

The first is the modeling concept. It starts with the simple idea that if you can draw a concept, in terms of pictures and arrows, or even build a crude toy representation of an idea, you might be able to crystallize nascent ideas into a more all-encompassing formulation. The concept of feedback in endocrinology is a classic example. The initial concept of the black box that somehow "knows" the result of its actions is an electrical engineering innovation. Since then teachers have borrowed it, and abused and distorted it, to describe the dynamics of the classroom. The first and foremost thing that feedback analysis points out is that the system is dynamic and not static. The present generation of researchers and students alike is hard pressed to realize the massive advance in thinking that simple notion represents, not only for engineering, but for teaching and biology alike.

More important prospectively, models provide the critical questions for both research and active therapy. You build your model, and it says "Now if you do this, then the following should happen." You have no alternative but to try the critical experiment.

Another form of model provides a case in point. It is highly efficient to talk about things in mathematical terms. The mathematical approach provides a continuous numerical check of theoretical prediction against experimental evidence. The researcher can not only measure the presence and extent of divergence between theory and practise, but can also estimate trends and shape further alteration. The work of Mordecai Schwartz in using a mathematical model of tumor growth[1] and the follow-up work of Blumenson, Bross and Slack in its application to breast[2] and endometrial carcinoma[3], as well as the work of Bayard, Clarksen and Fried[4] provide

excellent examples of the utility and applications of the mathematical model. As with any simulation method, the mathematical approach has its limitations, in particular that of the necessary reduction to the simplest mathematical form in order to ease the data manipulation. Nonetheless the method is powerful because it unambiguously defines the nature of the process in model terms. For example it is vastly more significant to say A is inversely proportional to B than it is to say A gets bigger as B gets smaller.

Engineers have always been greatly concerned with efficiency. Social pressures are such that doctors are rapidly becoming equally sensitive. To be efficient means to provide the maximum return for the minimum investment. Thus clearly the first problem for the efficiency-oriented doctor must be to define the return as well as the input. Which raises the interesting question of what is health. Before we are able to evaluate the quality of medical care, we must establish clear distinctions between health and disease. Doctors have never had to do this before. As a result no one can adequately define what good health is, nor is anyone able to obtain agreement on the definition of a good doctor. The question is of massive importance to governments and their citizens alike, not to speak of the doctors who serve them. For if the public is to pay the bill, then the public will sooner or later demand an accounting. Hence an operational definition of terms becomes a necessity.

Operations research is a branch of engineering which concerns itself with the design of efficiency as applied to men, materials and equipment. It's concern is not so much whether the motor runs efficiently, as whether the motor, and the machine it drives and the men who use and depend upon the motor work efficiently as a team. Traditionally operations researchers optimize the output from refineries, plan trucking routes and the like. More recently they have turned their attention to the delivery of health care. "What is the public getting for its health dollar?", is the initial question, but the analysis goes on from there. It currently begins to answer questions about the nature of health versus disease. Fanshel and Bush[5] have recently defined a health-status index which begins to resolve these problems. While they acknowledge that a person's health is the net result of a complex of factors, their health status index views health as a continuum on a single-dimensional scale of function/dysfunction. This definition allows the authors to define prognosis as the likelihood of moving from one functional state to another. The model is essentially economic in nature, which the authors acknowledge is a shortcoming, but nonetheless it constitutes a good first approximation to a long sought ideal. Interested readers are referred to their excellent article for further discussion and examples of its application.

Information theory is a mathematical outgrowth of electrical engineering and thermodynamics first developed by Shannon in 1947. Its concern is with the value of information, or to put it in clinical medical terms, it attempts to quantify the diagnostic or therapeutic value of a given test result.

Information can be operationally defined as something that causes an adjustment in a probability assignment. Inasmuch as medicine is continually faced with probabilistic situations, classical information theory has much to offer both clinicians and researchers. It says, for example, that a test result bears information only if it allows the recipient to alter his diagnostic probabilities.

Of greater importance, Shannon's concepts bring into the open a formerly subtle distinction having wide significance especially to community medicine.

During the 1950's and early 1960's the Kaiser - Permanente Foundation established a number of health facilities which were devoted to the then new practise of multi-phase screening. Whereas the doctor, when confronted with an ailing patient, is concerned with the question "What is wrong?", the designers of the Kaiser-Permanente clinics, workings with "normal" populations, were concerned with the significantly different question "Is anything wrong?". Traditional medicine has sought tests which are specific for given disease. There is, in clinical medicine, a high premium on the test that is considered pathognomonic. Such a test is considered to be highly *specific*. Generally speaking, such tests carry a considerable risk of false negativity. On the other hand, medical screening programs demand procedures which will demonstrate deviations from the normal with great sensitivity. The risk in this event is false positivity. The general principle of note can be stated simply: The more sensitive the test, the less specific it tends to be. Hence therapeutic physicians attempting to diagnose ailing patients use different tests than do screening physicians.

The engineering analogue of the sensitivity-specificity dichotomy is the photo-electric counter. The greater its sensitivity, the more frequently it records factitious impulses.

Shannon further points out that information has a cost. The idea was certainly not original with him, for Schrodinger pointed out some years previously that either the position or speed of an atomic particle could be determined, but not both, for the test itself altered the experimental situation. Hence, it is reasonable to expect that every test has a cost, and as well bears a certain measurable risk. If one defines the cost of a given test as the direct costs, both dollar and otherwise, *plus* the summed products of the probability of a given complication times the cost of that complication should it occur (in effect summing cost and risk), you can arrive at a cost-benefit ratio. For the public health official, the concern could be with the cost of diagnosing a case of phenylketonuria in the infant population[6]. For the therapeutic clinician, the concern might be the overall merit of a liver biopsy in a jaundiced patient. The lesson however is consistent. Each and every investigation bears a

cost and a risk which must be considered prior to the conduct of the test.

Thus it can be seen that information theory, modeling concepts, and efficiency criteria, though nominally of the realm of the engineer, can be profitably brought to bear upon medical problems. But the exchange need not be unilateral. The problems encountered in biology offer a subtle complexity which generally cannot be met with using relatively direct engineering techniques.

The Shared Comparison

Possibly the clearest lesson the engineer stands to learn from the clinician is that instruments have severe limitations. It is possibly true that a moderately skilled clinician can evaluate the status of a new patient faster than an engineer, using modern techniques, can measure the dimensions of a room. Both engineers and doctors are primarily concerned with taking measurements, and acting upon the data gathered thereby. Engineers, under the seemingly concrete conditions of the usual problem, tend to resort to direct methods, with an emphasis upon high significant digit precision. There is a dangerous tendency to believe figures rather than facts, and there is an equally dangerous tendency to emphasize precision rather than accuracy. One's concern must not be with numbers so much as with assuring that the numbers represent the phenomenon being investigated.

It has been said that the physician is the most sensitive transducer ever invented. The manner in which experienced clinicians can evaluate a patient in moments, clearly without deliberately enumerating all the signs and symptoms to be elicited, is a case in point. The physician, first and foremost, is a human and while he does not have the memory or instant recall of even a small computer, he is better able to manipulate and analyse information at hand than the most sophisticated electronic device.

Doctors in particular share a pungent awareness of the dynamic nature of systems. They know, from long experience, that no two situations are ever really the same, and that each situation demands at least a certain amount of individualization. They also know that intervention, in any form, alters the pre-existing situation and bears a significant risk. The concept of watchful expectation as practised in clinical medicine is the operational epitome of this realization.

Recently there has evolved the science of human factors engineering, the design of machines to fit the people who use them. One of the original problems human factors engineers tackled was the design of aircraft altimeters. Following a series of mysterious crashes in the late 1940's, detailed and repeated investigation showed that while the altimeters then in use were extremely precise, in that they could measure altitude within a few feet, they could not be read under ambient operating conditions. What was needed was clarity rather than needless precision. So, highly precise, mirror-backed arc dials were replaced by cylindrical dials with big, thick bars where the hair thin needles used to be. As a result, crashes of the former nature have not been repeated, and human factors have become legitimate and necessary considerations in aircraft design. A similar revolution is only now beginning in the automotive industry. Industrial pollution problems also raise similar considerations.

Thus it seems that both doctors and engineers stand to benefit from examination and in some instances adoption of the other methodology. But there are also areas where direct co-operation and shared expertise offer particular rewards.

Shared Responsibilities

It is well enough to borrow another profession's methodology. It is quite another thing to attempt intra-professional self-sufficiency. MD's who are also trained as professional engineers are not a solution to either medical or engineering-medical problems. At best they serve as catalysts or highly trained translators of professional jargon. What is more important is a shared understanding of methods of approach as applied to both medicine and engineering. If both engineers and doctors come to understand the strengths and weaknesses of each other's disciplinary approach, they will be better able to utilize their respective skills and bring to bear areas of their own particular strength to otherwise unapproachable problems. Furthermore, it is increasingly necessary that engineers and doctors acquire a common understanding of common problems. It is both frustrating and wasteful to approach a common problem with divergent understandings of that problem. There is a terrible tendency on the part of both professions to immerse uncertainty in a tangle of jargon. If joint solutions to any medical engineering problem are to be achieved, then the essential starting point must be a common understanding to both problem and goal of solution. This is as true of heart-lung machines as it is of computer diagnostic schemes.

Does the Scientific Method Suffice?

Both engineers and doctors share something else — a common investigative approach, the Scientific Method. The Scientific Method made possible the scientific revolution. It systematized science and made it reproducible But it has inherent serious shortcomings.

First, the method is predicated upon the identification of all significant variables. Inasmuch as the variables you identify are a consequence of the means you use to identify them, the parameters themselves are dependent upon the experimental environment. It is likely not possible to identify all significant variables prior to conducting the experiment.

Second, the situation where all variables save one are fixed is in itself an artificial extrapolation of reality. In nature, things do not change one at a time. They change

together, in some form of dependence. Statistical analysis is our rather weak effort to neutralize these uncontrollable alterations of variables known or occult.

What is really needed is a means of analysing and identifying more parameters than one at a given time. Not a new manipulation of old statistics, but an entirely new method of approach. The thrust must be toward facts rather than data manipulation. If biology is to be mastered this is essential.

This dissertation opened with the statement that it is easy to be both an engineer and a medical doctor, possibly even easier than to be a doctor and not an engineer.

Both disciplines have similar problem conformations. Methodologies are different, but there is room for hybridization. Engineers are trained to think in simple, clear terms, often to the point of suggesting that if a problem is endlessly immersed in complexity then it is not clearly understood. The engineer is committed to reducing a problem to its essential core, and then dealing with the facts as he sees them. Repeatedly the question is, "Is it important?".

Doctors are also problem oriented, but they are tempered by a well justified reluctance to grab at simplistic solutions to terribly subtle problems. There is much to be gained from each discipline by each discipline. Sometimes the benefit is merely a fresh, anti-environmental outlook. Occasionally the new approach offers a clear solution where there appeared to be none before.

It is in this sense that it is easier to be both an engineer and a doctor than to be either alone.

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R. I. Harris Prize

The Editors would like to announce that W. J. Peters has won the R. I. Harris prize for his article IMPLANT MATERIALS AND THEIR USE IN ORTHOPAEDIC SURGERY (March, 1972). This prize is awarded on an annual basis by the Orthopaedic Surgery Committee to the Author of the article judged the best written on a topic related to Orthopaedic Surgery. It has a value of $100. F.G.

Webster Prize

The winner of the Webster Prize for year 71-72 is Joseph Tokaruk, 7T2 for his article AEROPHAGIA OR GASTRIC GAS TRICKS (Gastroenterology issue, January, 1972). The prize is awarded to the undergraduate author of the article judged best in the *Journal* for that year. We congratulate Joseph and thank the Academy for continued interest in undergraduate journalistic and scholastic efforts. F.G.

Normal Gait And The Design Of Prosthetic Limbs

E. J. Rumble, 7T2

INTRODUCTION

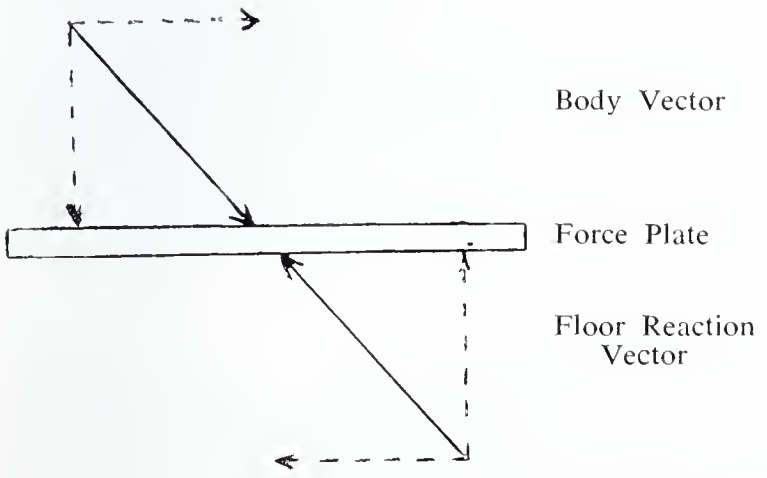
Prior to the Eighteenth Century, the amputation of a limb was an uncommon surgical procedure, as surgeons were unable to control massive blood loss. The amputees of that day were primarily the survivors of trauma, who managed to hobble around on crutches and makeshift peg legs. With the introduction of the ligature and the tourniquet, the rate of survival of surgical amputees rose, until by 1700 amputation of a limb was the most common surgical procedure in Europe. From that point until the present, the development of better prosthetic limbs has continued, but it was not until the Twentieth Century that engineers have applied their knowledge to the design of prostheses.

NORMAL GAIT

The ideal prosthetic limb would duplicate the function and appearance of the normal limb. In order to design a prosthetic leg, it is first necessary to have a thorough knowledge of normal gait.

If heel strike is defined as the point at which the heel first makes contact with the ground, then the gait cycle is defined as the sequence of movements of a lower limb between one heel strike and the next heel strike in the same limb. The gait cycle is 60% stance phase, during which the foot is in contact with the ground, and 40% swing phase.

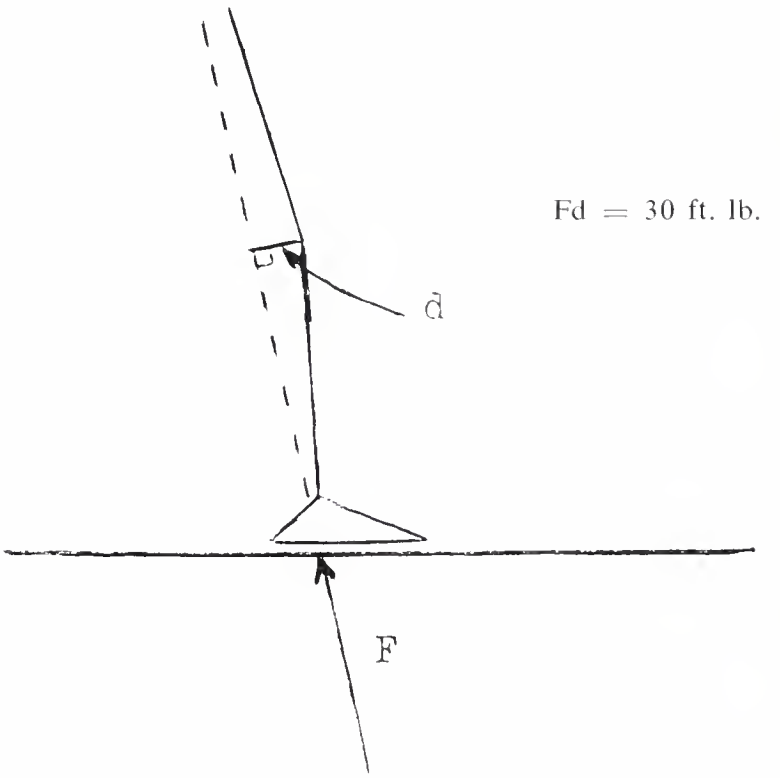
The gait cycle may be studied by the use of kinetics and kinematics. Kinematics is the precise description of the movement of the various parts of a body in relation to each other and to the environment. Kinetics is the study of the forces which cause these movements. Kinematics is studied by means of movies, videotapes, and electronic means of measuring angular and translational motion, whereas kinetics is studied by means of force plates, electromyography, instrumented pylons, and pressure transducers.



The force plate measures the forces applied to it in all three dimensions. If these forces are resolved into a single vector at a given instant in the gait cycle, that vector is called the floor reaction. By Newton's third law, the floor reaction is equal in magnitude and opposite in direction to the body vector.

It is this body vector which acts on the ankle, knee, and hip in the stance phase to cause movement. The movement at these joints is modified or opposed by the muscles in order to cause the sequence of movements we call walking.

For example, in the stance phase between foot flat and mid stance, the body vector is directed behind the knee; thus it acts to flex the knee. Its magnitude is such that the moment acting to flex the knee is 30 ft. lb.



Thus, it may be inferred that if the knee extensors develop 30 ft. lb. at this point in the gait cycle, no movement will occur around the knee joint, whereas more than 30 ft. lb. causes extension and less allows flexion to occur. In actual fact, it can be shown by movies that at this time the knee is slowly extending from 20° at foot flat to 15° at mid stance. Hence it may be inferred that the quadriceps are developing slightly more than 30 ft. lb. moment around the knee.

This is one important consideration in the design of a prosthetic knee joint. If the prosthetic knee is in the same position as a natural knee would be at this instant, and the same forces are acting on it, there must be a mechanism which provides an extension moment of 30 ft. lb. to prevent the knee from collapsing. Ideally this mechanism would provide slightly more than 30 ft. lb. in order to duplicate the action of the quadriceps. Furthermore, this mechanism would be able to provide a varying moment around the knee joint as it moves through the gait cycle and as walking speed changes. This ideal mechanism has not yet been devised. Many prosthetic

limbs manage to get around this problem by remaining in full extension or near full extension throughout the stance phase.

It would be much easier to design this ideal knee extension mechanism if it were possible to measure the force developed by the quadriceps. To this end, engineers have used an electromyograph (EMG), which measures the electrical activity of muscles. However, it has been shown that the force developed by a muscle does not correlate with the electromyographic activity. Nevertheless, the EMG does tell which muscles are acting at any given point in the gait cycle, which otherwise may not have been apparent. For example, the EMG shows one peak of quadriceps activity occurring immediately after toe off, during which movies show the knee is flexing, rather than extending. This part of the swing phase is called heel rise, and is caused by the inertia of the lower leg as the thigh is being accelerated by the action of the hip flexors. It occurs in prosthetic limbs as well as in natural limbs. In the absence of an extension mechanism, the heel would rise so high that forward motion of the body would have to pause for a moment to allow the lower leg to come forward to be in position for the succeeding heel strike. Thus, a prosthetic extension mechanism is necessary to duplicate the action of the quadriceps in preventing excessive heel rise.

The kinematic and kinetic analysis of normal gait is presented in Fig. 1.

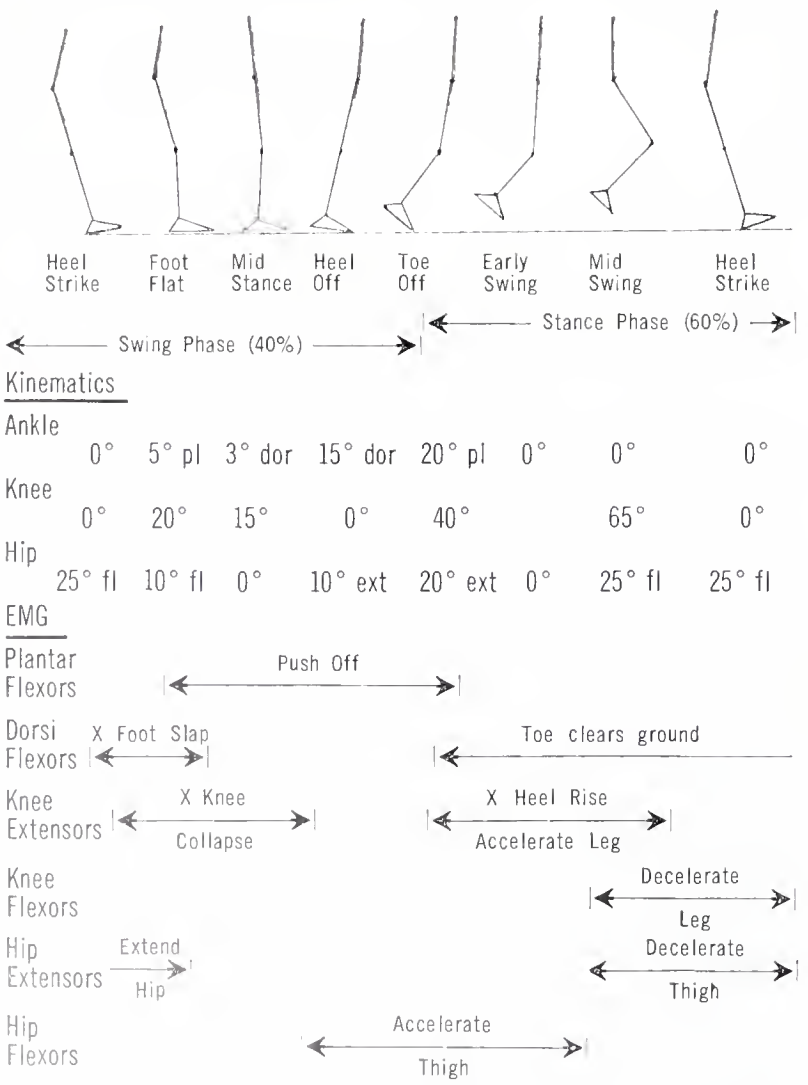


Fig. 1 — Kinematic and kinetic analysis of normal gait.

ABOVE KNEE PROSTHESIS

The best example of the application of engineering principles in prosthetic design is the Above Knee (AK) prothesis.

The components of an AK prosthesis are:

Socket and Suspension Mechanism

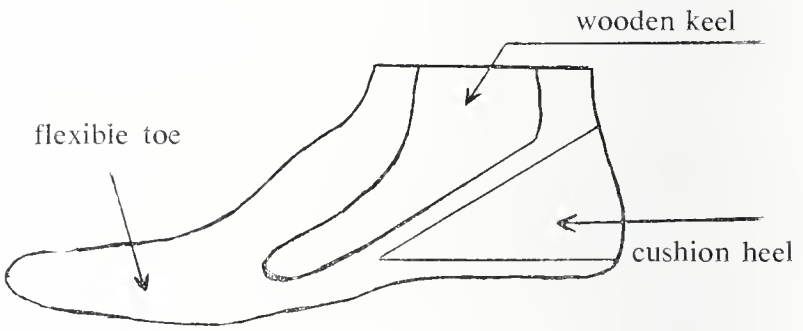
Knee Mechanism

Shank

Foot and Ankle Mechanism

1) *Foot and Ankle Mechanism*

In practice the foot piece is not articulated to the shank; rather it is one solid piece. The ankle function is served by a sponge rubber wedge inset into the heel, and a flexible toe piece. This is called a SACH (Solid Ankle Cushion Heel) foot, and is prescribed in about 90% of cases in North America.



The heel inset serves the function of the dorsiflexors in absorbing some of the shock at heel strike, preventing foot slap, and maintaining the swing phase foot in the neutral position so that it clears the ground. The flexible toe functions as a plantarflexor in that it allows resisted dorsiflexion at heel off; nevertheless, it cannot produce the push off which is necessary for a normal gait. To date, no push off mechanism is available.

2) *Shank*

This is often only a solid pipe (pylon) connecting the knee to the SACH foot, with a cosmetic shell around it.

Since heel rise occurs because of the inertia of the shank and SACH foot as the thigh is accelerating forward, it is important to make this part of the prosthesis as light as possible to minimize heel rise. Indeed, it is important to make the entire prosthesis as light as possible to minimize the effort required by the amputee in walking.

3) *Knee Mechanism*

The most common knee joint is a single axis hinge. In order to duplicate a more normal gait pattern, a flexion and extension mechanism must be incorporated.

Normally, the extensors function in the stance phase to prevent knee collapse on weightbearing and to extend

the knee, and in the swing phase to prevent excessive heel rise, and to accelerate the lower leg. In the prosthetic limb, collapse of the knee is prevented by either proper alignment of the limb in the sagittal plane, or by incorporation of a lock or friction mechanism in the knee joint. By proper alignment it is meant that the body vector is directed in front of the knee axis in the sagittal plane during the stance phase thus maintaining the knee in extension.

Numerous joint mechanisms are available in which friction is applied to the knee joint when weightbearing, thus preventing collapse of the joint even though it may be in flexion and the body vector behind the knee joint axis in the sagittal plane.

Most amputees require an extension aid to inhibit excessive heel rise and to accelerate the swing phase of the limb. This can be done by incorporating an elastic extension strap or compression bar in the knee mechanism, or more recently, hydraulic or pneumatic swing phase controls which are adjustible to different walking speeds.

The knee flexors function to decelerate the leg as the knee approaches full extension, just before heel strike. This prevents the sharp impact which would otherwise occur. This function is served in prosthetic limbs by the friction device in the axis of the knee, which can be adjusted to not only prevent extension impact, but also to inhibit heel rise.

4) *Socket*

The socket adds yet another joint to an already multi-jointed limb. Ideally, no motion should occur at the socket-stump interface in any direction, as forces are applied to it during the gait cycle. This is best accomplished by first making the amputation stump as long as possible, and then making the prosthesis in such a way that the walls rise as high as possible without interfering with hip movement. The fit of the socket to the stump should be snug enough to resist movement; this is important both for socket-stump stability and for suspension.

The tissues at the end of an amputated stump will not tolerate much weightbearing. The socket is moulded in such a way that the entire stump is in contact with its walls; this is called a total contact socket. This tends to distribute the weight over a much greater area, thus reducing the mean pressure on the tissues of any given area. Furthermore, the socket is shaped in such a way that areas capable of bearing more weight do so; the anterior surface of the thigh, for example, can bear weight more comfortably than Scarpa's Triangle. Most weight, however, is borne on a natural weightbearing structure: the ischial tuberosity. The posterior rim of the socket sits snugly up under the ischial tuberosity, so the amputee in a sense 'sits' on the prosthesis during the stance phase.

5) *Suspension*

During the swing phase, there must be some provision to keep the prosthesis from falling off the stump. A common method is suction. A one way valve in the lower end of the socket allow air to be expelled from the socket during the stance phase, thus creating a negative pressure in the swing phase. In addition, some amputees wear a strap around their waist or over their shoulder for added security.

SUMMARY

The kinetic and kinematic characteristics of normal gait have been described, indicating areas which present problems to the designers of prosthetic limbs.

The design of comomnly used components of the above knee prosthesis have been briefly outlined, indicating the designers' approach to some of these problems.

It is apparent that the design of the modern prosthetic limb is far from satisfactory. Several problems remain as yet entirely unsolved. Continuing study and research into better approaches to the stump-prosthesis connection, and better ankle and knee joints will go far to improve the rehabilitation of lower limb amputees.

ACKNOWLEDGEMENT

I would like to thank Dr. J. P. Kostuik, Orthopaedic Surgeon, Toronto General Hospital, for his assistance in the preparation and writing of this article.

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Futures In Health Education In Ontario

R. Reid, 7T2

This article will discuss a few of the current trends in health education in Ontario and will indicate where, possibly, these trends are taking the medical community. A significant document in determining a policy for health education is the report of the Task Force on Future Arrangements for Health Education. Beginning in November of 1970, the task force investigated, as its primary objective, the need for a sixth health sciences complex in Ontario. Further, the task force was asked to consider the concept that a new health science complex might initiate new, non-traditional approaches to health education in an attempt to modify the traditional methods of health care delivery.

The task force, as with any government body, did not operate in a vacuum. It was subject to many outside influences including those of the medical and paramedical professions, including the Ontario Medical Association, College of Physicians and Surgeons, the Faculties of Medicine, Nursing, Dentistry and Pharmacology, the universities, students in health sciences and others. Outside the professions, the Provincial and Federal Governments through their Departments of Health, health care consumers and other groups with various special interests care about the direction which health education takes. Any attempt to place these various groups into their respective places and chart their relationships with one another would be too complex to undertake here. One important body in this complex system and the body which created the Task Force on Future Arrangements in Health Education is the Ontario Council of Health. The Council is the senior advisory body to the provincial Minister of Health and thus, according to its terms of reference, to the government of Ontario in "Matters pertaining to comprehensive health services for the people of Ontario". This body, reporting directly to the government, has considerable influence in all areas of health. Included within its mandate is health education.

As a result of the terms of reference given the task force and also considering the concept of regionalization of health services previously formulated by the Council of Health, the task force had to consider two areas in relation to health education in the future. First, emerging patterns in health care might necessitate changes in the numbers and types of health workers. These new patterns would cause changes in the structure and function of a new health science complex. Secondly, the task force considered the mythology of numbers especially with regard to the physician/population ratio and to the expected population increase in Ontario.

In the past few years new methods and new personnel in health care delivery have appeared. These developments and their continuing growth and emergence will necessarily affect medical education. The formation of large group practices such as the Permanente groups in the United States has led to the dispersal, to some extent, of highly qualified specialists to smaller centers and to a rise in the academic standards in these areas. As well, prepaid medicare such as the Kaiser plan has led to an increase in the accessibility of care. The extensive use of automated and computerized facilities has resulted in increased efficiency and in generally better health care. Some critics of these polyclinics bewail the 'dehumanization' of medicine. However, these clinics attempt to bring a patient back to the same physician on every visit if possible, to a general practitioner in charge of his case who will generally supervise the entire program. To this extent, it is dehumanized; a single patient may see a large number of physicians during his visit to the clinic, each specialized in a certain area. However, he will be assured of their competence to deal with a particular problem and will not be forced to depend on a single, solo practitioner who is trying to cover all areas of medicine. Most groups of any size provide within themselves the opportunity for ongoing education both formally and informally. As well, most groups provide members with the opportunity to attend meetings and conferences in other areas.

The new emphasis on ambulatory care and preventive medicine as opposed to acute or hospital - centered therapy may eventually bring about a de-emphasizing of acute therapy and a shift in medical education towards office practice, home care and preventive medicine. As well, this new emphasis may lead to the building of government-financed clinics offering total health care. These clinics might take a form similar to those envisioned in the Castonguay Report: clinics containing physicians, nurses, laboratories, welfare facilities and others will offer both medical and social care to the public. Such clinics will cause change in the practice of medicine and this change must result in changes in medical education.

The United States is just now witnessing the emergence of a new health care worker. Different names, qualifications, training and responsibilities are given to these workers. However, they are most commonly referred to as physicians' assistants or nurse practitioners. Many are nurses, while significant numbers are former armed forces medics. In the U.S.S.R., Feldshers have been active for years and are an established part of the health care system. Generally in the United States, the training period is two years, depending on previous qualifications. In Canada a course for nurse practitioners has been started at McMaster University and presently has approximately twenty students.

There are many questions to be answered. When these particular health workers graduate, where will they work? What will they do? What responsibilities will they have? How will they be paid? As yet no firm ideas exist as to these graduates' place in the present scheme of medical care. How will they relate to physicians and how will physicians relate to them? One pattern which might develop is one in which the nurse practitioner,

working for a physician as a salaried employee, will be occupied with the routine aspects of a practice such as well-baby clinics and long-term follow-up of hypertensives. This pattern is developing in some areas of the United States. At present, it is too early to predict what will happen in Ontario, although the experience with nurses working in isolated areas of northern Ontario suggests the possibility of staffing small clinics with nurse practitioners who would have access to physicians in a larger centre. The emergence of this class of "near-physicians" will require profound changes in the attitudes of medical practitioners; and, as most of a physician's attitudes are formed in medical school, the teaching in medical school will have to adjust.

The inherent message in medical education is one which designates the physician as the "head of the team" and invests in him all responsibility for the patient. The rest of the health-care team is held as subservient to the physician to a greater or lesser extent. If the utilization of medical services continues to increase at the present rate, physicians will be forced to delegate authority and responsibility. If this approach is taken, the nurse practitioner or equivalent is the present person to whom increased responsibility could be given. Another approach is to increase the number of physicians available. However, this approach is much more costly in terms of training, time, and money. If the nurse-practitioner approach is taken, the actual structure of the various health sciences' curricula may become integrated.

A student interested in health care might begin his career in a common course for the first few years. This course would enable him to continue to any given level, to change to another course and to associate with all of the health workers of all qualifications with whom he will later work. The advantages of streaming are many, but the main ones are the flexibility in career choice offered and formation of a "team" through having common courses. Streaming within medical schools already exists; again, in the United States, where students can choose options fitting them for careers in research or in practice. This plan could easily be expanded to include those primarily interested in surgery, medical education, or public health, thereby allowing earlier specialization but always maintaining flexibility. The approaches outlined above are at present mainly proposals, but some of these proposals have already been put into practice. What will be the outcome of these experiments and their final effects is not yet known.

The second approach taken by the task force concerned man-power and the need for university health sciences centres to be responsible for both health education and for health care delivery in their region. At present there are approximately 10,000 physicians in Ontario. This number provides a physician/population ratio of 1/745, which compares favourably with that in countries with a similar standard of living. The total loss to Ontario of physicians is approximately 3% per year and the population is growing at approximately 2% per year. Thus, Ontario will need to add physicians at an annual rate of approximately 5% in order to maintain our present physician/population ratio. Current plans for the expansion of Ontario's medical schools would bring the output to approximately 5% per annum. If the plans for expansion formulated by the task force are put into motion, output would rise to approximately 8% per year, thereby improving the physician/population ratio. As well, continued high immigration of physicians to Ontario is likely to continue and thus improve the ratio even further. However, the problem of maldistribution of physicians requires remedy, and it is this problem which will require further effort to solve.

Plans formulated by the task force project the following future graduating capacity for Ontario's medical schools:

University	*Graduating Class*
Toronto	350
Western	150
Ottawa	130
McMaster	130
Queen's	100
Total	860

The increase in number of students at Toronto envisages the use of satellite teaching centres both within the city and in the university's region. This expansion presupposes the expansion of preclinical facilities on the main campus.

The concept of regionalization of health care may be fully examined in the document listed in the bibliography, and a few words of explanation are all that is required here. The Committee on Regional Organization of Health Services recommended the formation of regional and district health councils in the province. The regional council is to be comprised of the chairmen of the district councils within a region, a representative from the region's health science centre, a representative from the regional or local government and others from among the primary groups and those with special experience or knowledge pertaining to health or health services. The district councils are to include representatives from local government, consumers of health care, voluntary agencies and persons from the health professions. Regions and districts are to be delineated by the provincial government, and generally a region would be centred around the university health science centre which will be the reference base for the region. The closer ties thus formed between the health science centre and its region will have an effect on medical education.

Regionalization will undoubtedly lead to the sending of health science students to peripheral clinics within a region for large parts of their education. This implies greatly expanded communication facilities and clinical facilities in areas previously unused for undergraduate education. As well, regionalization should lead to a more equitable geographic distribution of medical personnel

within a given region. The time spent in an area as an undergraduate has an undoubted effect on the area in which a graduate later sets up a practice. As well, the presence of students in an area will provide a stimulus for local students to enter the health-care professions. Regionalization and the required increase in contact between science centre and its satellites will also enhance the ongoing education of practising physicians in the area.

The future of medical practice is now being determined, as is the future form and content of medical or health education. At present, too many forces are exerting influence to make any firm predictions on future medical practice possible. Health education is being forced to respond to the demands which are being and which will be made upon it. The eleven recommendations of the Task Force on Future Health Arrangements for Health Education provide a basis for much discussion and many approaches to fulfilling the recommendations. These approaches are now being formulated and will be in effect in the next decade, and we will have to adjust to them.

RECOMMENDATIONS

It is recommended:

1. THAT no new health sciences complex be built until the capacity of existing institutions has been fully developed and attempts have been made to integrate health education and health care delivery.
2. THAT necessary resources be committed to the established health sciences complexes so that they can begin developing and implementing the programmes that are necessary for new developments in health education and health care delivery and that this have the highest priority in the utilization of resources.
3. THAT these new developments include the establishment of satellite health education centres (involving hospitals, clinics, doctors' offices and other health units), within the guidelines for regionalization recommended by the Ontario Council of Health, so as to provide (a) a base for health education oriented to community health problems, (b) an increase in clinical facilities (including ambulatory care) for the education of health personnel, and (c) an increase in resources for continuing education of health personnel, so as to provide first rate services integrated with the educational programme.
4. THAT the satellite education centres be distributed and organized so that they can exert a positive influence on the selection of students, the regional distribution of health manpower, and the participation of users of health services.
5. THAT the health sciences complexes maintain their educational programmes as far as is possible on a year round basis, with the objective of reducing the length of time required to graduate individuals from the programmes and to attain maximum utliization of personnel and facilities.
6. THAT in implementing these new programmes it is essential that the universities and government jointly establish a control mechanism to ensure that the resources are used to achieve these objectives.
7. THAT new arrangements for funding the operating portion for the education of health personnel, including the associated clinical services within the health sciences complexes, be established.
8. THAT in keeping with the guidelines for the development of health technology programmes, there be established in respect to the education of health personnel in each region a regional advisory planning committee for the health sciences complex (composed of representatives from the health professions, education, government and the community).
9. THAT in order to improve the mobility of students in the various health education programmes and the efficient use of resources, the educational programmes of the colleges of applied arts and technology, schools of nursing and universities be closely integrated.
10. THAT the government and universities recognize in the development of new programmes that the established function of the university in scholarship and research should be maintained and that success will be achieved only by blending new programmes with the scholarship and creativity within the university.
11. THAT at regular intervals after the initiation of a new programme for the education of health personnel, the situation be reviewed by the Ontario Council of Health in respect to the progress made by the established health sciences complexes and the organization of health services by community groups.

ACKNOWLEDGEMENT

The author would like to thank the members of the Task Force on Future Arrangements for Health Education and the Chairman, Dr. J. F. Mustard for the opportunity to serve on the task force.

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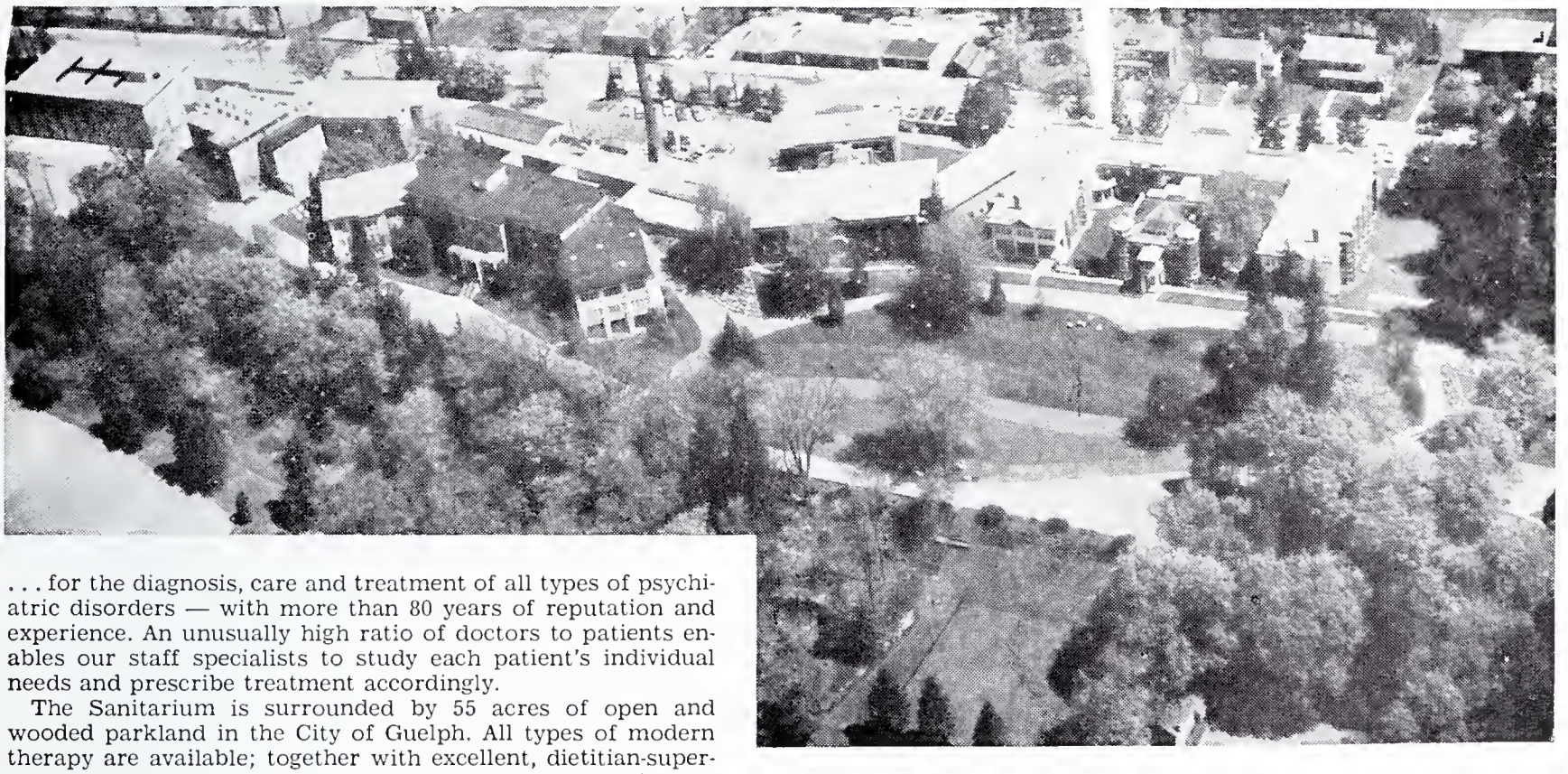

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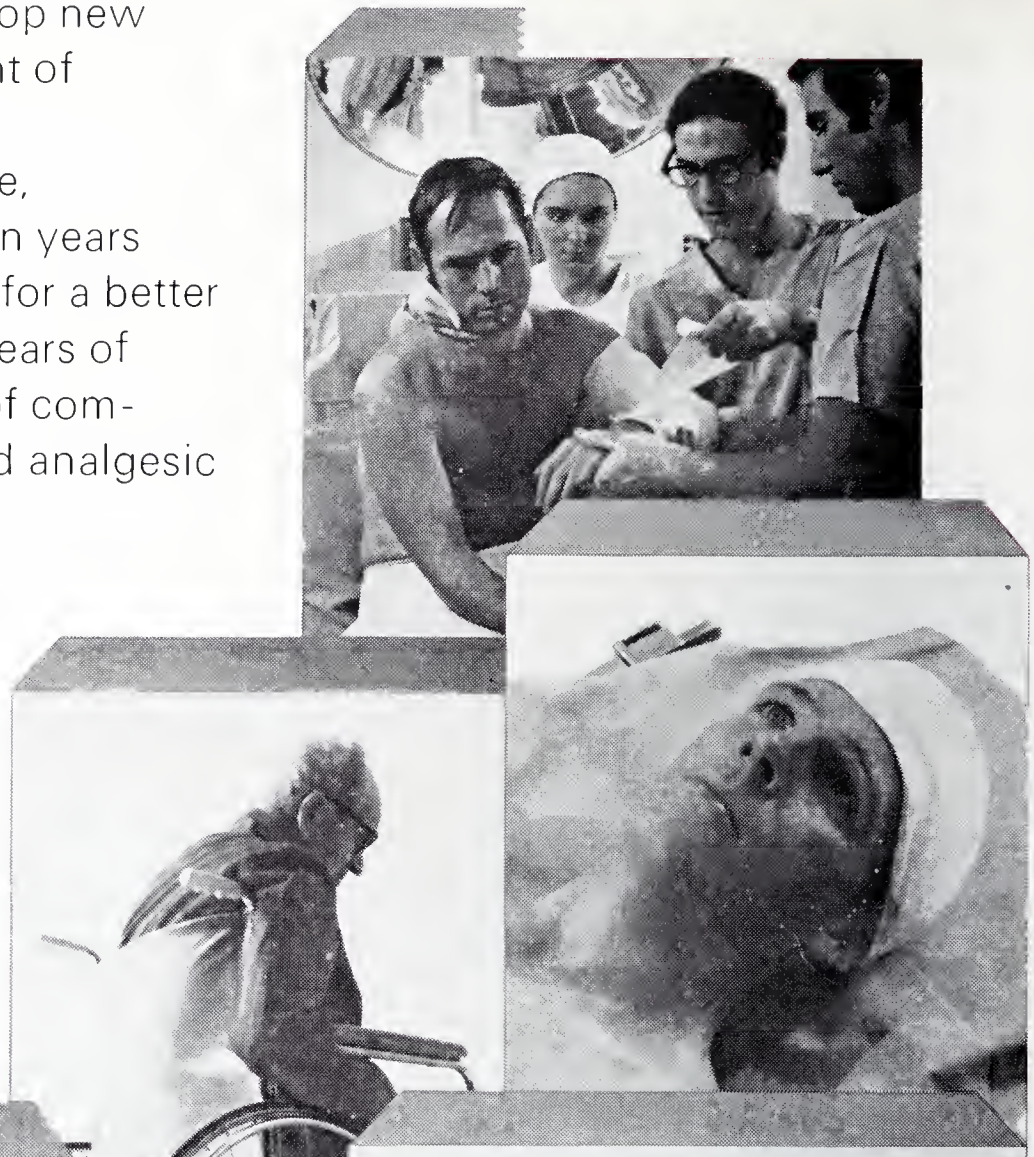

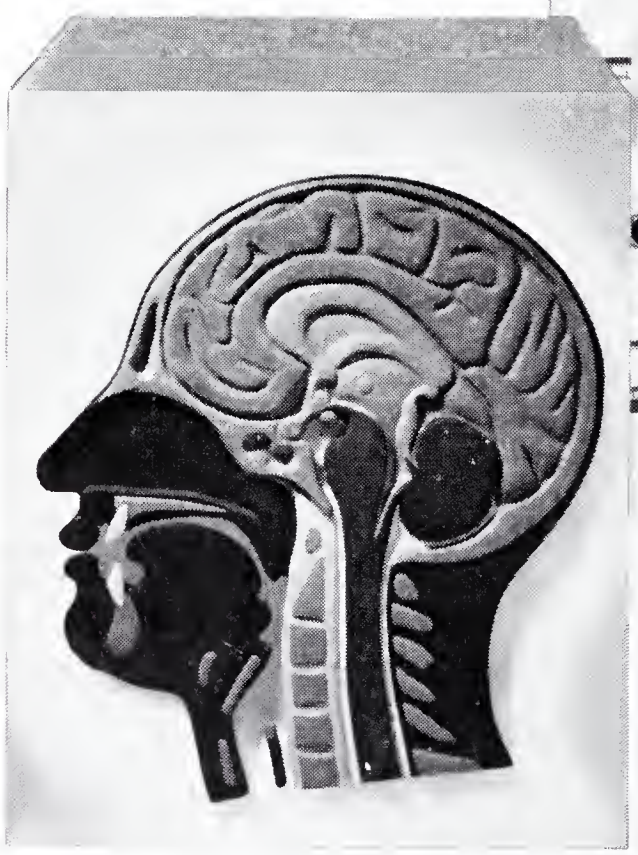

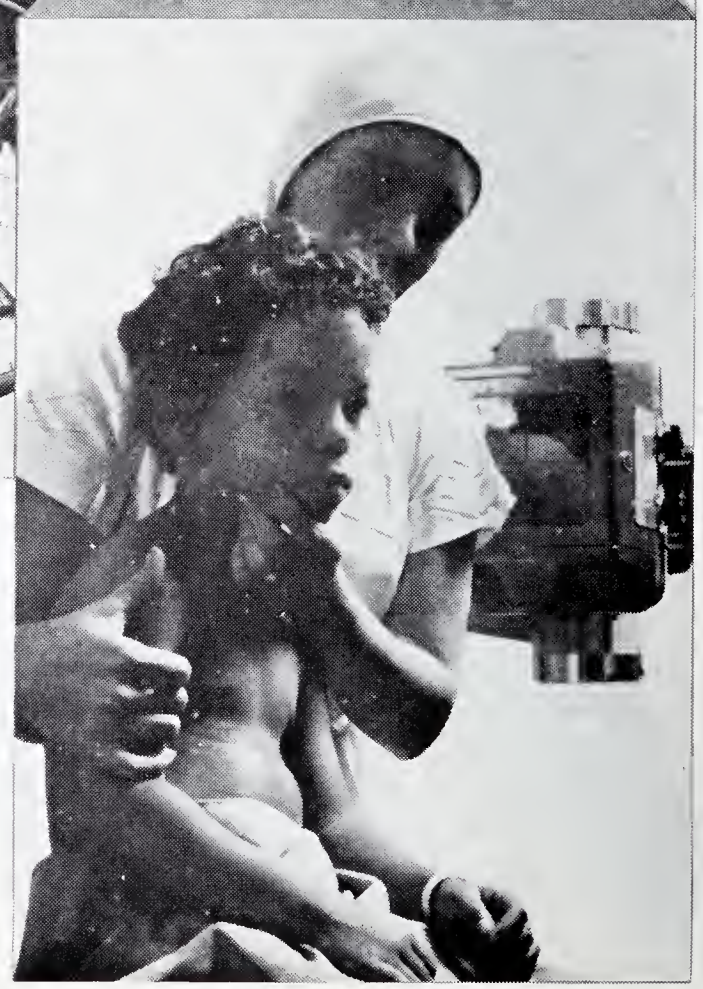

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